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Interregional Meeting on Co-operation among Developing Countries for the Development of the Pharmaceutical Industry

New Delhi, India, 19-22 March 1990

REPORT *

* This document has not been edited.

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INTRODUCTION

1. The Interregional Meeting on Co-operation among Developing Countries for the Development of the Pharmaceutical Industry was held at New Delbi, India, from 19 to 22 March 1990. It was attended by 58 participants from 14 countries and 6 representatives of 3 international and other organizations (see Annex I). The Meeting was held at the invitation of the Government of India.

Background to the Meeting

2. UNIDO organized three Consultation Meeting on the Pharmaceutical Industry at Lisbon (Portugal), Budapest (Hungary) and Madrid (Spain) in 1980, 1983 and 1987, respectively. At these meetings the participants emphasized the importance of develoipng domestic pharmaceutical industry covering pharmaceutical formulations, biologicals, pharmaceutical chemials and drugs based on medicinal plants. These meetings took into account the factors involving policy and production measures and identified a number of issues involved in the promotion and development of this industry in developing countries.

3. As a follow-up to the recommendations of the Third Consultation, UNIDO planned to convene an Interregional Meeting on Co-operation among Developing Countries for the Development of the Pharmaceutical Industry in New Delhi. The Meeting was to discuss and reach conclusions on topics ranging from industrial drug policy, research and development, integrated approach to the development of the pharmaceutical industry, establishment and development of national, regional networks for exchange of information, experience and development of human resources, and industrial utilization of medicinal plants including herbal medicine, and thus to set a stage and create an atmosphere for action-oriented recommendations, and promote cc-operation among developing countries for the development of the pharmaceutical industry.

I. ORGANIZATION OF THE MEETING

Opening of the Meeting

Statement by the representative of UNIDO

4. The Chief of Process Industries Unit, System of Consultations Division, speaking on behalf of the Director of the System of Consultations Division of UNIDO, expressed the Organization's deep appreciation to the Government of India for hosting the Interregional Meeting on Co-operation among Developing Countries for the Development of the Pharmaceutical Industry. The Meeting, he said, was a reflection of the increased focus by UNIDO on industrial activities that meet the fundamental needs of people of developing countries ensuring both the immediate and long-term welfare of society, impact on health, social well-being and economic performance. He said the objective of the Meeting was the development of guidelines for strategies and policies concerning the integrated development of the pharmaceutical industry in developing countries. The promotion of the pharmaceutical sector was warranted in both preventive as well as curative medicines. The Meeting was thus to consider subjects ranging from steps associated with the development of industrial drug policies, problems faced in undertaking and executing an integrated approach towards the development of the pharmaceutical sector including industrial utilization of medicinal plants, setting-up of an information network for exchange of technical information, human resource

development, enhancement of overall expertise, development of mechanisms for co-operation in R&D capabilities and promotion of regional co-operation among developing countries in mutually beneficial areas of the pharmaceutical industry with the aim of improving the economic exploitation of local resources.

Statement by the Secretary, Department of Chemicals and Petrochemicals

5. Mr. M.S. Gill, Secretary to the Government of India, Department of Chemicals and Petrochemicals, welcomed the participants to New Delhi. He apologized for the absence of the Minister of Chemicals and Petrochemicals at the inauguration ceremony due to unforeseen and important State engagement. The Secretary to the Government of India said that the Meeting was in fulfilment of a mandate given to UNIDO by the Third Consultation on the Pharmaceutical Industry to encourage interregional co-operation among developing countries in the pharmaceutical sector and particularly in the field of plant-based medicine. He expressed his thanks to UNIDO for accepting India's suggestion to convene the Meeting in New Delhi. He mentioned that the Interregional Meeting was being held at a time when India was in the process of reviewing her drug policy in order to make it more pragmatic with the intention of channelizing higher investment and better technologies into this sector. He expressed the hope that the deliberations of the Meeting would be helpful to India in appreciating the totality of the situation and taking the necessary policy measures with the objective of encouraging the growth of the pharamaceutical sector in his country, the pharmaceutical requirements of which were expected to increase by 500% by the turn of the century. He said that most of the participating countries have similar kinds of experience and problems, thus that Meeting would indeed be a right and useful forum where mutual problems could be understood and in co-operation with each other issues could be tackled. Referring to the need for making scientific advance in the area of herbal medicine, the Secretary pointed out that imaginative steps needed to be taken for better exploitation in this area in order to overcome finanical constraints facing health systems and to benefit humanity at large in all countries. He emphasized the need for information and establishment of an information network on the herbal system of medicine.

Statement on behalf of the Minister of Petroleum and Chemicals

6. In the absence of the Minister of Petroleum and Chemicals, his speech was read on his behalf by the Joint Secretary in charge of the Pharmaceutical Industry, Government of India. The Minister welcomed the representatives of UNIDO, WHO and UNESCO and the participating countries. He highlighted the importance of human health and the need for international co-operation in the development of the pharmaceutical industry which he emphasized should be viewed in a global context. Describing UNIDO as an apex organization he urged UNIDO to help developing countries in acquiring and improving technologies in all industrial sectors, particularly in the pharmaceutical sector. He emphasized the need for industrial research and development efforts and exchange of information amongst countries. He talked about the importance of the traditional system of medicine and urged for its development along scientific lines.

Election of officers

7. The following officers were elected:

Chairman: M.S. Gill (India), Secretary to the Government of India, Department of Chemicals and Petrochemicals

Vice-Chairmen: B.E. Rao (India), Director (Production), Indian Drugs & Pharmaceuticals Ltd. (IDPL)

E.N. Mshiu (Tanzania), Director, Traditional Medicine Research, Muhimbili Medical Centre, University of Dar-es-Salaam

K. Hüsnü Can Baser (Turkey), Director, Medicinal Plants Research Centre, Anadolu University

Rapporteur: R.N. Tandon (India), Joint Director (PI), Department of Chemicals and Petrochemicals

Statement by the Vice-Chairman of the Meeting

8. The Vice-Chairman of the Meeting noted the importance of the Meeting and emphasized the significance of the pharmaceutical industry. He outlined the role of UNIDO and drew the attention of participants to the main topics for discussion which included industrial drug policy, integrated development of the pharmaceutical industry and industrial utilization of medicinal plants. He drew attention to the documents prepared by UNIDO for the Meeting.

Adoption of agenda

9. The Meeting adopted the following agenda:

1. Opening of the Meeting
2. Election of Chairman, Vice-Chairmen, Rapporteur
3. Adoption of agenda and organization of work
4. Presentation of topics by UNIDO Secretariat and consultants:
   - Industrial drug policy
   - Development of the pharmaceutical industry and industrial utilization of medicinal plants
   - Factory-produced herbal medicine - the Indian experience
   - Medicinal plants for therapeutic use - the Indian experience
   - Guidelines for the testing of herbals/herbal preparations
   - Setting-up of data bases on medicinal plants
   - Development of an integrated pharmaceutical industry
   - Establishment and development of a network for exchange of information and experiences"
   - Technological and economic co-operation in selected areas of the pharmaceutical industry
   - Identification of technical co-operation projects
5. Discussion of the topics
6. Adoption of conclusions and recommendations
7. Closing of Meeting

Documentation

10. The documents issued prior to the Meeting are listed in Annex II.

Adoption of conclusions and recommendations

11. The report on the conclusions and recommendations of the Meeting was adopted by concensus on 22 March 1990.

Concluding statements

12. At the closing session, the Government of India was thanked for its hospitality and the efficient way in which the Meeting was organized, which had contributed to its success. A number of participants noted the spirit of goodwill and understanding that had prevailed during the Meeting. A representative from the African region and another from India expressed willingness to host the forthcoming Regional Consultation on Medicinal and Aromatic Plants. The Vice-Chairman of the Meeting in his closing remarks thanked the delegates for their active participation, creation of a climate of trust and co-operation and valuable results of the Meeting.

II. REPORT OF THE PLENARY SESSION OF THE MEETING

Presentation of topics

13. Members of the UNIDO Secretariat and UNIDO consultants introduced the background papers on the topics to be discussed by the Meeting according to its approved agenda (para. 9) followed by extensive discussion and exchange of experience by the participants. The subject matter of the topics concerned industrial drug policy - the Indian experience; key aspects of industrial utilization of medicinal plants including medicinal plants for therapeutic use; factory-produced herbal medicine - the Indian experience; guidelines for testing of herbals/herbal preparations; setting-up of data bases on medicinal plants; possible issues for the proposed Regional Consultation on Industrial Utilization of Medicinal and Aromatic Plants; Development of an integrated pharmaceutical industry; establishment and development of a network for exchange of information and experience; technological and economic co-operation in selected areas of the pharmaceutical industry.

Presentation by the representative of WHO

14. The representative of WHO welcomed the co-operation and understanding that existed between UNIDO and WHO. Referring to the potential value of traditional medicine, he pointed out that in the last three years the World Health Assembly had passed three resolutions in support of the utilization of medicinal plants in the health services systems of its Member States. One of the resolutions urged Member States to ensure the quality control of medicines derived from traditional plant remedies by using modern techniques and applying suitable standards and good manufacturing practices. This resolution reaffirmed WHO's commitment to work with UNIDO in this important area. He said that the application of modern scientific methods in the cultivation, selection, manufacture and clinical trial of herbal medicine is the most appropriate way of transforming traditional trade into modern industrial practice. In this connection, the Chinese, Japanese and Indian models along with other model that may be identified by UNIDO and WHO, could be considered by other countries. In view of the potential economic value of medicinal plants he emphasized the need to strengthen data gathering and analysis capabilities with a view to industrial applications. He reiterated continuation of efforts to strive towards finding the best ways of working together for the benefit of Member States and recalled the common pledge of WHO and UNIDO made at the Third Consultation on the Pharmaceutical Industry in 1987 where it was agreed to assist developing countries in conducting

pharmacological and clinical studies on plant-derived products to ensure regulatory requirements for safety and quality control; conduct special educational programmes to publicize the proper use of plant-derived herbal medicine; organize Consultations at regional levels on various facets of the medicinal plant industry.

Presentation by the representative of UNESCO

15. The representative of UNESCO welcomed the co-operation that existed between UNIDO and UNESCO in the area of scientific and technical information systems. He described UNESCO's role in promoting the dissemination of information and knoweldge. He gave a brief account of UNESCO's approach to information system development and said that the system revolved on (i) emphasis on users-oriented information services; (ii) appropriate use of information technology; and regional and sub-regional co-operation.

16. Another representative of UNESCO made a presentation on the working of APINMAP (The Asian Pacific Information Network on Medicinal and Aromatic Plants). He said that the Centre was located in Bangkok and offered voluntary co-operative programmes for countries in the Asian and Pacific region. The principal objectives of APINMAP included:

1. Promotion of information exchange in the field of medicinal and aromatic plants;
2. Establishment on a continuous basis of necessary linkage with regional and international organizations in similar or related fields to (a) ensure optimal utilization of exiting resources; and (b) avoid duplication and overlapping of research activities.

17. While explaining the working of APINMAP, he invited the participants to express their views on the approach followed by UNESCO. He also briefly described the proposed International Chemical Information Network which was being promoted in collaboration with UNIDO. The activities of the project were planned to be directed towards exchange of experience, specialized studies, directives, contacts among developing countries to improve information services, development and promotion of methodologies for training information specialists and users.

Summary of discussions

18. National experience in the development of the pharmaceutical industry and evolution of industrial drug policy was the subject of statements made by some participants.

19. Many participants stated that there was a need to increase local production of pharmaceutical formulations, pharmaceutical chemicals and their intermediates in most of the developing countries. They emphasized that steps are necessary to facilitate transfer of technology, enforce quality controls, enhance research and development capabilities and develop human resources.

20. Commenting on the price control on pharmaceuticals, one participant observed that free and fair competition and not the price control was the answer to uninterrputed availability at reasonable prices of pharmaceuticals and this would assure economic viability of the pharmaceutical industry. Others emphasized the need to achieve maximum availability of medicine to the public through some form of price regulation.

21. One participant expressed the view that protection of indigenous production as well as the objective of self-sufficiency and backward integration can be better achieved through suitable tariff and pricing mechanisms.

22. One participant said that developing countries through a spirit of mutual co-operation can support each other by procuring raw/finished materials from amongst themselves; the encouragement through mutual trade was considered vital for the development of the pharmaceutical industry.

23. A representative of the Indian Drug Manufacturers' Association made an offer for negotiations on the availability of technology for the manufacture of formulations and pharmaceutical chemicals and their intermediates.

24. One participant underlined that WHO's goal of Health for All by the Year 2000 can only be achieved if industrial production of plant-based traditional medicine was encouraged and upgraded through scientific evaluation, development of standards for raw and finished products using modern techniques and instrumentation and exchange of information.

25. One participant highlighted the need for inclusion of herbal medicine in the folds of industrial drug policy.

26. Some participants stated that use of modern methods and equipments needs to be encouraged in formulation production of herbal medicine.

27. A few participants emphasized the need for developing guidelines for good manufacturing practices for factory-produced herbal medicine.

28. The need for setting-up data bases on medicinal plants was the topic of interventions by many participants.

29. One participant said that interested developing countries should provide data regarding their country to UNIDO for free exchange with other countries related to the availability of medicinal plant resources (both modern drugs and traditional), list of preparations based on medicinal plants, technological status with regard to manufacturing facilities, system of registration, R&D programme, national policy on medicinal plants. The interested countries should also indicate their needs in terms of economic survey for collection/preservation of plants, technology needed for processing plant materials, assistance in developing legislation to foster the use of herbal medicine in the health care system. The aim of such information should be promotion of co-operation in technical, institutional and financial fields.

30. Many participants stated that the use of medicinal plants has been the core of practice of traditional medicine in most developing countries. It was noted that some of these plant species were on the verge of extinction. Attention was drawn to taking co-operative steps for the conservation and cultivation of these plants.

31. A few participants stated that the mandatory inclusion of the study of phytotherapy in the curricula of medical education will facilitate the ready acceptance by practitioners of scientifically produced herbal preparations on prescriptions.

32. Participants endorsed the issues submitted by UNIDO for consideration at the proposed Regional Consultation on the Industrial Utilization of Medicinal and Aromatic Plants.

33. The representative of ACDIMA made an offer to host one of the preparatory expert group meetings for the Regional Consultation, at the premises of ACDIMA Headquarters in Amman, Jordan.

34. A number of participants stressed the importance of manpower training in various disciplines of the industry. A few participants made known the training facilities which were available in their countries.

35. One participant stated that the Government of Turkey, in collaboration with UNIDO, was conducting a training programme entitled "Training in the Utilization of Medicinal and Aromatic Plants in the Pharmaceutical and Related Industries (TRUMAPI). The programme consists of theoretical and practical aspects of production and quality control of medicinal plant-related industrial activities.

36. A few participants requested UNIDO and WHO's assistance in establishing data bases on traditional herbal drugs, promotion of research on herbal drug industry, establishment of institutions for carrying out safety and efficacy studies on herbal drugs, establishing an international body of experts for formulating uniform criteria for standards to be followed by drug authorities of member states for acceptance of herbal products for registration.

37. Representatives of the UNIDO Secretariat described the organization's current programme of technical assistance, technology transfer, and programme of activities of the Centre for Genetic Engineering and Biotechnology in Italy. UNIDO was involved at various stages ranging from conducting of feasibility studies to commission of plants in the sector. The experience and know-how was available to interested developing countries.

38. A performa entitled "Request for Special Assistance" was circulated to participants for return to UNIDO by interested delegates. Many participants presented such requests, some of which were taken care of immediately by the host authorities on bilateral assistance bases, others were referred to UNIDO.

39. One participant stated that potent plant materials were now available after scientific evaluation and in-depth work on traditional medicine for diseases such as viral hepatitis, filariasis, anal fistula, bronchial asthma, antistress, anti-urolithiasis, for which no single categoric remedy was still available. He stressed the need for active work on these diseases and the available potent plant-based materials.

40. One participant stressed the importance of developing a regulatory framework for integration between the traditional and the modern system of medicine utilizing modern and traditional drugs. He also drew the attention towards the need for evaluation of marine flora and fauna as a possible source of new drugs, intermediates and/or lead molecules.

41. A few participants stressed the importance of an integrated approach to the development of the pharmaceutical industry. A representative of UNIDO highlighted the assistance that the organization has provided in developing a Master Plan for the Development of an Integrated Pharmaceutical Industry to some of the interested developing countries.

42. The importance of South-South co-operation was subject of discussion by some participants. They highlighted the need for technological and economic co-operation among developing countries in the areas of setting-up an information network, transfer of technology, research and development, engineering services, joint venture production facilities, marketing and

development of human resources. They called upon international organizations for providing assistance in implementing activities in the above-referred areas.

43. In the context of technological and economic co-operation one participant stated that there was an ample scope of such co-operation amongst developing countries because of the cost and currency factor. He referred to the low-cost Indian manufactured machinery for manufacture of pharmaceutical formulations. He also highlighted the possibilities of co-operation in the manufacture of standardized herbal extracts and production of phytochemicals, such as Ajmalcine, Vinblastine, Valepotriates, products of Podophyllum.

44. Referring to a practical example of technological and economic co-operation among developing countries, the representative of ACDIMA, a Pan-Arab company, made a presentation on the working of ACDIMA which has so far established ten pharmaceutical plants and one R&D centre in Arab countries. The example could serve as a fore-runner for establishing similar set-ups on co-operative basis in other regions.

AGREED CONCLUSIONS AND RECOMMENDATIONS

45. Products of the pharmaceutical industry play a strategic role in sustaining the health and well-being of the population, which is essential for the performance of their social and economic activities. "Medicinal plants-based products" continue to be therapeutically important for a large segment of the world's population, especially in developing countries.

46. The local pharmaceutical industry plays an important role in keeping the supply of medicine at an adequate level. In order to achieve health care objectives and industrial development goals at the national level, close co-operation and co-ordination between those responsible for health and industry along with agencies responsible for human resource development are required.

47. Very few developing countries could claim to have the capabilities to provide for their own drug needs through local production of biologicals, pharmaceutical formulations, pharmaceutical bulk drugs/chemicals, intermediates and products based on medicinal plants. The economic feasibility of producing most essential drugs would require a level of demand far beyond the absorptive capacities of a large number of developing countries' markets. Therefore, effective development of the pharmaceutical industry would require active co-operation between developed and developing countries, as well as among developing countries themselves.

48. Moreover, in order to allow healthy and smooth development of the local pharmaceutical industry and at the same time fulfil national health objectives, a delicate balance must be struck to accommodate both these objectives through pricing mechanisms and other systems of incentives. In fact, in most countries having a pharmaceutical industry, it was found necessary to adopt a "national industrial drug policy" within the framework of the national health policy and the national industrial development policy in order to achieve harmony between their short- and long-term objectives.

49. Considering the increasing complexity of the pharmaceutical industry and the challenges brought about by the new advances in frontier areas of related science and technology such as genetic engineering and biotechnology, an integrated approach to its development needs to be adopted in which the industry is viewed in the context of its socio-economic technological and all

other related aspects of development. It would thus be necessary to look into factors that have some bearing on the development of the industry without necessarily being within its boundary. In such an approach, the technically and economically motivated backward or forward integration of various industrial activities would need to be considered as well as co-ordinated with other socio-economic activities such as population growth and its structure, health related policies, education, infrastructure, etc.

50. The national industrial drug policy should aim at:

- Increasing local production of pharmaceutical products including production of formulations, bulk drugs (pharmaceutical chemicals), chemical intermediates and raw materials;

- Standards and quality control of all pharmaceutical products as well as in-process controls;

- Research and development, both basic and process research, needed for the development and progressive indigenization of the industry;

- Price regulation of the products in order to maintain the availability of supply at an appropriate level and at the same time to provide adequate incentives for the development of national supply sources;

- Development of national capabilities related to human resources, technical expertise, ancillary industry, engineering capabilities for process development and local manufacturing of equipment and fabrication of processing equipment;

- Ensuring technology transfer and assimilation and its upgradation on a continuing basis.

51. In order to improve the economy of production and to ensure a consistent level of supply, it is important to integrate the pharmacuetical industry in the national productive system in such a way as to obtain the necessary inputs it requires from within the country in the form of raw materials, chemicals and intermediates, auxiliary materials, packaging materials as well as research and development support activities, manpower development scheme, local engineering and equipment fabrication capabilties. Such an approach would provide a tightly knit national production chain with a maximum degree of internal economic and technological self-sufficiency and complementarity.

52. The practical tool to make effective the application of the above approach is formulating a model scheme for the development of an integrated pharmaceutical industry. Such a scheme should present a general concept that takes on a specific character when applied to the concrete situation of each developing country. Basically, it provides for the estimation of the demand for pharmaceuticals and tries to equate it to supply, with particular emphasis on the promotion and development of local production. It is a working tool for technical experts, financial specialists, planners and decision makers, containing pertinent data and recommendations needed for the creation, rationalization and development of a local pharmaceutical industry. It further makes transparent to all concerned the basic conditions and requirements, the interdependence of ancillary industries, the necessary infrastructure, the appropriate institutional framework and the corresponding legal provisions and procedures. The scheme clarifies the long- and short-term goals and identifies specific investment projects for their attainment. It can become part of the national development plan and be integrated in the national health care policy.

53. It has been recognized that the most effective way in which the development of the local pharmaceutical industry in developing countries could be achieved is through the integrated approach, whereby the industry is viewed within the framework of a national development policy/national health development plan/national industrial drug policy plan and that it is manifested in a model scheme outlining the development objectives of this industry in the long and medium terms. A critical analysis of the demand and availability of local resources to meet this demand sets the basis for the development of local sources of supply to meet the expected demand for different types of drugs and services and associated industries, taking due account of the cost effectiveness, strategic objectives and long-term national economic development goals. Special emaphsis is given to the rehabilitation/ modernization of existing productive assets, their retooling or expansion and the installation of new prdouction capacities, backed up by through feasilbility studies indicating the amount of investment, the type of technology and government regulations and incentives required for their implementation.

54. Considering the difficulty of obtaining process technology for the production of pharmaceutical chemicals in developing countries on the one hand, and the poor economic viability of producing such chemicals for a limited market on the other, UNIDO's concept of multi-purpose plant for the production of pharmaceutical chemicals in developing countries could be resorted to. The multi-purpose plant concept is a viable approach for developing countries that wish to enter into the flexible manufacture of a number of pharmaceutical chemicals in quantitites compatible with the requirements of the local market. Even more important, it creates the physical facilities for the transfer ot technology and know-how and the training of local personnel in chemical synthesis and research and development capabilities.

55. The creation of a viable industrial sector with ample potential for self-sustained growth in a country or a region calls for the parallel development of all of the mutually complementary and supportive activities, including ancillary industries. Local production of packaging materials would have obvious advantages for the pharmaceutical and the general industrial development of developing countries, particularly in view of the shortages of foreign exchange. The promotion and development of pharmaceutical-related ancillary industries, such as those producing paper, cardboard, glass, plastic and metal-based packaging materials, offer specific benefits to the pharmaceutical industry.

56. Plant-derived medicines form an important component of health care in developing countries. In rural areas in particular, where the availability of pharmaceuticals is least, plant-derived medicaments are in widespread use. Therefore, this important therapeutic resource should be fully utilized in any strategy for the development of the pharmaceutical industry.

57. The approach towards accomplishing this must recognize that considerable R&D would be needed prior to inclusion of plant-derived medicaments within the national health care programme. Such R&D should be aimed at:

- Validating traditional remedies using modern scientific techniques, including biological methods;
- Developing methods and standards for assessment of quality and stability;
- Developing new medicaments, particularly for conditions for which no suitable modern therapies are available;
- Upgrading processing technology; and
- Identifying new chemical structural models for modern drug development.

58. Such strategies must also be cognizant of the fact that a variety of disciplines should be co-ordinated in plant-derived drug development and that trained human resources in all disciplines must be available for the purpose.

59. Given the increasing interest in many industrialized as well as developing countries in all "naturals" as opposed to synthetically produced products, an opportunity is afforded for developing countries to utilize suitable technologies in the processing of safe and quality tested plant-derived pharmaceuticals for global marketing.

60. The systematic crop-wise cultivation and genetic improvement of plant resources for use in industrial scale processing is necessary not only for maintenance and ensurance of raw material supplies but also to ensure uniformity of quality.

61. Many developing countries possess to a substantial degree the necessary scientific infrastructure required for development of technology reaching towards industrial processing of plant-derived medicines. However, since they lack the facilities to do so, UNIDO's versatile polyfunctional pilot plant design would be a suitable means to help them. Thus, UNIDO should continue its efforts in this field and try to implement in developing countries the plant which it has designed.

62. It was recognized that access to the current world's proliferating literature on plants, their constitutents, methods of analysis etc. was a necessary requirement for the development of plant-derived pharmaceuticals. Accordingly, UNIDO has now taken the initative with UNESCO and WHO to develop a comon database accessible to scientists, technologists, entrepreneurs and policy makers in developing countries, to collate and disseminate information on medicinal and aromatic plants.

63. The Meeting considered that South/South co-operation constitutes a major element in the development of the pharmaceutical industry in developing countries and as such it agreed on the need to establish a regular mechanism for technological and economic co-operation among developing countries on the following:

- Information networks and databases including possible establishment of sub-regional and regional information networks;
- Training of manpower resource development, including the use of national training facilities and their possible conversion and use as regional centres;
- Research and development activities including basic and operational research;
- Engineering services and supply of machinery and equipment fabrication;
- Establishment of joint venture production facilities and co-operation in production; raw material and chemical trade and marketing arrangements;
- Exchange of experience on enterprise-to-enterprise and national levels and institutionalizing this activity on a regular basis.

64. The Meeting <u>recommended</u> that:

(a) Developing countries wishing to advance the development of their pharmaceutical industry adopt an industrial drug policy within the framework of a national health care policy on the basis of which they ensure the development of the national pharmaceutical industry. Such a drug policy should include plant-derived medicines and ancillary industries. While the aim of such a policy is to ensure the availability

of supply of medicines to the population, particular care should be taken at the same time to guarantee the smooth development of the national pharmaceutical industry and the encouragement of indigenous research and development activities;

(b) UNIDO, upon request, should help developing countries in the elaboration of a national industrial drug policy on the basis of the integrated approach for the development of the pharmaceutical industry;

(c) UNIDO, in collaboration with UNESCO and WHO, should assist developing countries in the establishment of national information databases on the pharmaceutical industry including plant-derived medicines and that sub-regional and regional data networks should be established to collectively aid the developing countries. The information system should collect, manage and disseminate information on medicinal and aromatic plants and plant-derived preparations, taking account of the needs of all potential users including those involved in research and development, training, decision-making and production and make such information and methods of its handling available as far as possible, to other Member States;

(d) In view of the importance of plant-derived medicaments, developing countries should integrate these medicament systems in their national health care system.

65. The Meeting endorsed the proposal to hold a Consultation meeting on the development of industrial utilization of medicinal and aromatic plants and proposed that the main issues of such a Consultation should focus upon:

(a) Strategies and methodologies for the industrial utilization of medicinal and aromatic plants and the setting-up of a phytopharmaceutical industry;

(b) Establishment of mechanisms for sub-regional, regional and international co-operation for:

(i) Preservation, propagation, cropwise cultivation and genetic improvement of medicinal and aromatic plant species and the exchange of germ plasma;
(ii) Development of technology for processing of plant materials including the implementation of the design of the versatile polyvalent pilot plant developed by UNIDO for processing of plant materials;
(iii) Establishment of standards and methods of quality assessment;
(iv) Collation and exchange of information and the establishment of a referral database;
(v) Conducting pharmacological, pre-clinical and clinical studies;
(vi) 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.

66. UNIDO and WHO should collaborate in efforts to review presently available procedures for biologically evaluating the efficacy, toxicity and stability of plant-derived medicaments and should -

(i) Identify procedures which are suitable for incorporation in quality control protocols in the phytopharmaceutical industry;
(ii) Develop protocols for new pharmaceutical preparations based on plants;

(iii) Suggest a mechanism for standardization of selected bioassay procedures so that they may be adopted by the phytopharmaceutical industries in developing countries;

(iv) Identify possible institutions and personnel in developing countries who may be assigned the above tasks (i to iii);

(v) Provide assistance to developing countries in the development and implementation of drug regulatory requirements;

(vi) Identify and develop known therapeutically active plant-derived substances as a means to augment national essential drug requirements; and

(vii) Assist Member States in the indigenous production of pharmaceutical grade auxiliary materials such as starch, glucose, gums etc. so as to save scarce foreign exchange.

67. UNIDO should respond to requests by Member States to:

(i) Assist developing countries in ensuring adequate resources of medicinal plants required for processing including their genetic improvement;

(ii) Assist in the development of technology required for the creation of modern phytopharmaceutical industries in developing countries to manufacture standardized plant extracts or pure phytochemicals for use in the health care system;

(iii) Strengthen research and development institutions in developing countries to enable them to serve the needs of a phytopharmaceutical industry in the multi-disciplinary requirements of the industry, paying special attention to human resource development;

(iv) Include within its programmes a programme for the industrial processing of pharmaceuticals and chemicals derived from marine flora and fauna in order to assist Member States endowed with substantial sea coasts;

(v) Initiate the preparation of a set of comprehensive guidelines for the chemical and biological testing of plant-derived medicines.

68. Considering the importance of ECDC and TCDC, UNIDO should institutionalize fora for experts of developing countries in the pharmaceutical industry to exchange experience and information in the fields of:

(i) Operation of processing plants, quality assessment and plant maintenance;

(ii) Human resource development;

(iii) Multidisciplinary R&D;

(iv) Common problems in technology acquisition;

(v) Inclusion of phytotherapeutic methods in universities' curricula;

(vi) Information on sources of supply of raw materials, chemical intermediates, including their specifications, technology, machinery, etc.

Annex I

LIST OF PARTICIPANTS

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Annex II

LIST OF DOCUMENTS

- Economic and technological co-operation in the pharmaceutical industry	ID/WG.502/1/Rev.1(SPEC.)
- Data bases on medicinal plants	ID/WG.502/2(SPEC.)
- Development of an integrated pharmaceutical industry, prepared by the UNIDO Secretariat	ID/WG.502/3(SPEC.)
- Factory-produced herbal medicine - The Indian experience	ID/WG.502/4(SPEC.)
- Guidelines for the chemical and biological assessment of herbals and herbal preparations	ID/WG.502/5(SPEC.)
- Plant-derived therpeutic agents	ID/WG.502/6(SPEC.)
- Industrial drug policy - The Indian experience	ID/WG.502/7(SPEC.)
- Establishment and development of regional network for exchange of information, experience and training in the pharmaceutical industry	
- UNIDO standard specifications for a versatile, multi-purpose plant for the treatment of medicinal and aromatic plants	