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CONTACT

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Workshop on the Industrial Utilization
of Medicinal and Aromatic Plants
Milan, Italy, 24-27 March 1992

R E P O R T *

* This document has not been edited.

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Table of contents

	<u>Page</u>
Introduction	1
Background to the Workshop	1
I. ORGANIZATION OF THE WORKSHOP	2
Opening of the Workshop	2
Election of officers	3
Adoption of agenda	3
Documentation	3
Presentations	3
Concluding statements	4
II. AGREED CONCLUSIONS AND RECOMMENDATIONS	5
A. Conclusions	5
B. Recommendations	6
Annex I: Agenda	8
Annex II: List of documents	9
Annex III: List of participants	10

Introduction

1. The System of Consultations is an instrument through which UNIDO serves as a forum for decision-makers, industrialists, technical specialists, industrial investors, representatives of workers and manufacturers associations, etc. from developed and developing countries in their contacts and consultations directed towards the industrialization of developing countries with the objective of raising the developing countries' share in world industrial output through increased international co-operation.

2. Benefits deriving from this activity include the identification of obstacles to industrial development in developing countries, monitoring of trends in world industry with a view to identifying action-oriented measures for increasing the industrial output of developing countries and the search for new forms of international industrial co-operation in North-South and South-South relations.

Background to the Workshop

3. UNIDO organized three Consultation meetings 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 development of the domestic pharmaceutical industry covering pharmaceutical formulations, pharmaceutical chemicals, biologicals and drugs based on medicinal plants. The Consultation meeting held in Madrid (Spain) from 5-9 October 1987 laid special emphasis on the industrial-scale utilization of medicinal and aromatic plants. This was in view of the importance of these plants as source of therapeutic agents and contributor towards the health-care programmes and economies of both developed and developing countries. UNIDO was called upon by the Consultation to assist developing countries in co-operation with the World Health Organization (WHO), other United Nations agencies, and industry in the industrialized countries, in the development of various aspects of the industrial utilization of medicinal and aromatic plants to develop the subsector in a systematic manner.

4. In the above perspective and within the scope of the recommendations of the Third Consultation, as well as keeping in view the convening of the forthcoming Regional Consultation on the Industrial Utilization of Medicinal and Aromatic Plants, a Workshop was held in co-operation with INDENA/Inverni della Beffa Group, Milan, Italy. The objectives of the Workshop were: to exchange information on the development potential of industrial utilization of medicinal/aromatic plants, to hold discussions and highlight the kind of problems faced by developing countries in undertaking and executing an integrated approach towards the development of the subsector dealing with the industrial-scale utilization of medicinal/aromatic plants, to discuss initiatives leading to development of indigenous skills and technology for the processing, quality assurance, safety considerations, human resource development, regulatory arrangements and promotion of co-operation at all levels with the aim of economic exploitation of local resources.

I. ORGANIZATION OF THE WORKSHOP

5. The Workshop on the Industrial Utilization of Medicinal and Aromatic Plants was held in co-operation with INDENA/Inverni della Beffa Group at the premises of Istituto per il Commercio Estero (ICE) in Milan, Italy, from 24 to 27 March 1992. It was attended by 25 participants from 12 countries as well as by a representative of the World Health Organization (WHO).

Opening of the Workshop

Statement by the representative of UNIDO

6. The Director of the UNIDO Investment Promotion Office in Milan, speaking on behalf of the Director of the System of Consultations Division, welcomed the participants and thanked INDENA/Inverni della Beffa Group for their co-operation with UNIDO in hosting the Workshop. He also thanked the representative of the World Health Organization for the intellectual contribution and co-operation extended for the Workshop. He briefly explained the activities of UNIDO and in particular of the System of Consultations and the Industrial Investment Divisions. He touched upon the topics planned for discussion at the Workshop and hoped that the discussions would provide an opportunity for exchange of information and experiences and would contribute towards enhancing co-operation between developed and developing countries and amongst developing countries in the subsector. He also advised that the Regional Consultation on the Industrial Utilization of Medicinal and Aromatic Plants for Asia and the Pacific was planned to be held in March 1993. He wished the Workshop every success.

Statement by the Director-General of INDENA

7. The Director-General of INDENA welcomed the international participants, the UNIDO Secretariat, the representatives of WHO and ICE to the Workshop. He invited all participants to act in a simple and pragmatic way when looking at the problem of how best to utilize the country's potential in medicinal plants. He laid emphasis on two aspects. Firstly, the need for all-out efforts for utilization of local flora and traditional medicine to produce herbal medicine and remedies for local inhabitants. He said that adherence to the World Health Organization's Guidelines on Assessment of Herbal Medicine could be of great assistance in transforming a plant from the forest into a box of tablets containing standard extracts on the counter of a pharmacy. Secondly, he pleaded to developing countries to use local information on traditional medicine for patenting a new modern remedy through contracts of secrecy with parties in developed countries. He declared that INDENA offered itself as one of the candidates for such collaboration. He applauded the role played by UNIDO in providing opportunities for co-operation at various levels. He assured the participants of all assistance in making the Workshop a success and achieving the goals it has set for itself.

Statement by the representative of the Istituto per il Commercio Estero (ICE)

8. The representative of ICE, Milan, welcomed the participants. She noted the importance of the Workshop and expressed best wishes for successful deliberations in order to arrive at conclusions of significant importance for the subsector in the best interest of humanity.

Election of officers

9. The following were elected as officers:

Chairman: D. Bonacorsi
Vice-Chairmen: A. Bonati
B.N. Dhawan

Adoption of agenda

10. The Workshop adopted the agenda as per Annex I.

Documentation

11. The documents issued prior to the Workshop and papers presented at the Workshop are listed in Annex II.

Presentations

12. The UNIDO Secretariat made the following presentations:

- Issues in the integrated development of industrial utilization of medicinal and aromatic plants in developing countries;
- UNIDO's activities in the field of industrial utilization of medicinal and aromatic plants;
- Technology options in the processing of medicinal and aromatic plants and use of polyvalent processing plant.

13. The experts from INDENA made the following presentations:

- Production of phytopharmaceuticals (assessment of flora, quality assurance, technology);
- An overview of the approach adopted by the European industry and EEC for the evaluation and control of phytopharmaceuticals;
- Demonstration and discussion on practical aspects of processing technology.

14. The participant from WHO made a presentation on "Guidelines for regulatory needs for introduction of plant-derived medicine into the public health delivery system - Assessment of herbal medicines".

15. Eleven papers from ten countries were presented which covered:

- Assessment of medicinal plants potential; current situation and future prospects of industrial utilization of medicinal plants, information networks on medicinal plants and plant-derived products;
- Status of activities related to research and development;
- Information related to processing units and extent to which technology is being used and major problems and constraints faced for the development of this industry;
- Existence of a regulatory and registration system of herbal products, quality control arrangements, impact on the national health delivery system with explanation on education and training programme;
- Marketing and export potentials of medicinal plants, intermediates and finished products.

16. The presentation of country papers made by the respective participants covered the following countries: Cameroon, People's Republic of China, Egypt, Guatemala, Indonesia, Republic of Korea, Madagascar (2), Nigeria, Thailand and Turkey.

Concluding statements

17. At the closing session, INDENA/Inverni della Beffa Group and their staff were thanked by the representatives of UNIDO, the WHO and the participants for the hospitality and efficient way in which the Workshop was organized, which had contributed to its success. The spirit of goodwill and understanding that had reigned during the discussions was noted with satisfaction. The representative of the participants thanked the UNIDO Secretariat for the hard work done in connection with the preparation of the Workshop. The Chairman of the Workshop thanked the UNIDO Secretariat as well as the participants for their active participation and valuable results of the Workshop.

II. AGREED CONCLUSIONS AND RECOMMENDATIONS

18. The conclusions and recommendations of the Workshop were adopted by consensus on 27 March 1992.

A. Conclusions

1. Medicinal and aromatic plants play an important role in health care programmes and economies of both developing and industrialized countries.

2. In the case of medicinal plants, standardized procedures for chemical and biological assays, safety evaluation and controlled clinical trials have to be applied to plant-based traditional drugs to ensure consistent quality and acceptability by medical profession and the regulatory agencies.

3. It was noted that it is generally more difficult to register herbal medicines in developing countries than in industrialized countries. Hence appropriate steps should be taken to rectify the situation.

4. While safety should be an important criterion for the herbal medicine, it is necessary for the national regulatory bodies and registration authorities to evolve guidelines suitable for their particular needs. In this respect, the Guidelines for the Assessment of Herbal Medicine issued by WHO in 1991, as well as the Guidelines for Quality Control developed by the EEC in 1989 should be adapted to local needs.

5. To improve economics of the subsector, there is a need to upgrade cultivation techniques and improve production technologies.

6. A careful assessment of resource potential and constraints is essential to formulate strategies and policies promoting investment and ensuring adequate returns to developing countries, for many of which this is a vital resource. It is necessary to develop guidelines for secrecy agreements, licensing procedures, patents and intellectual property rights, etc. for plant-based medicine to encourage interaction between research institutions and industry.

7. Formation of manufacturers and professional associations related to the sector in developing countries where such bodies do not exist should be encouraged as these would accelerate industrial development of plant-based industries.

8. The health needs of developing countries demand that primary attention be given to introduction of standardized plant-based medicine in the health care programme. On the one hand, it will provide useful inputs for improving the quality of health, on the other hand, it will lead to development of plant-based pharmaceutical industry.

9. It was noted with concern that increased use of spontaneously growing flora is leading to decreased availability and even threatening the extinction of some species. Adequate conservation strategies need to be evolved urgently.

10. It was concluded that a regional and integrated approach can offer new opportunities to increase financial and industrial co-operation. Therefore, the need to build up regional capabilities in addition to national ones for development of plant-based medicine was stressed. The participants strongly favoured strengthening present national information and research centres and setting-up of regional/interregional research and development centres, offering information exchange, testing facilities, pilot plant facilities, training of manpower and research and development facilities.

B. Recommendations

Considering the above conclusions, the participants recommended that:

1. Developing countries should take appropriate policy measures to promote the growth of the plant-based medicine industry, preferably within the framework of a national/regional strategy for the overall development of the industrial sector and in particular the pharmaceutical industry. In this respect, developing countries should consider establishing national policy and planning committees to facilitate systematic development of plant-based medicine industry and formulation of requirements for registration of such medicine. International organizations such as UNIDO, WHO, FAO, ITC and regional organizations, such as ASEAN, ANDEAN, CEAO, COPPTEC, etc. could be called upon to assist on such aspects as formulation of industrial policies, methodologies for integrated approach towards the development, cultivation, genetic improvement, conservation, acquisition of technology, analytical and pharmacological standards, toxicity preclinical and clinical studies, R&D, legislation and registration of drugs and marketing of products, etc.

2. Steps should be taken to strengthen existing centres and wherever not available establish new national institutes/centres for the development of plant-based medicine. These institutes should set up and promote national standards and specifications, total quality control of products and processes, stability studies, establishment of reference standards, and undertake preclinical and clinical studies. Moreover, UNIDO should assist in the strengthening of existing institutions or the establishment of new regional/interregional centres. It was also emphasized that collaboration between private and public sectors should be encouraged.

3. Developing countries should draw up a list of medicinal plants which need to be investigated on a priority basis. WHO and UNIDO should play an important role in guiding and establishing such a list on a national/regional/interregional basis.

4. In order to protect individuals, institutions and countries providing information on which drug development programmes are initiated, WHO, UNIDO and WIPO should develop guidelines on patents, patent rights and intellectual property rights for adaptation by the countries concerned.

5. Appropriate new international co-operation schemes should be developed to foster and increase the flow and dissemination of information, new technologies and undertaking of joint ventures between developed and developing countries for the production of plant-based medicine.

6. Special attention should be paid to the development of human resources. UNIDO, WHO, FAO, ILO, ITC and other organizations should assist developing countries in the establishment and strengthening of training facilities at national and regional/interregional levels and organizing special training programmes to achieve human resource development.

7. In the area of R&D, strengthening of national capabilities and co-operation at regional and international levels in all disciplines of the medicinal plant-based industry should be enhanced.

AGENDA

24 March 1992

- 8.30 - 9.30 Registration
9.30 - 10.45 Opening of Workshop, Election of office bearers, Adoption of Agenda
11.00 - 11.45 UNIDO's activities in the field of industrial utilization of medicinal and aromatic plants (T. De Silva)
11.45 - 12.30 Production of phytopharmaceuticals (assessment of flora, quality assurance, technology) (E. Bombardelli)
14.30 - 16.00 Presentation and discussion of country papers on the status and prospects of industrial utilization of medicinal plants (S. Wasuwat, A. Molokhia, D. Hargono)
16.30 - 17.30 Continuation of presentation of and discussion on country papers (H. Baser, A. Saravia)

25 March 1992

- 9.00 - 10.30 Continuation of discussion on country papers (Yan Sun, Chang Seung-Yeup, M.M. Iwu)
10.45 - 11.15 Discussion on the issues in the integrated development of industrial utilization of medicinal and aromatic plants in developing countries (M.A. Majid)
11.15 - 12.30 Technology options in the processing of medicinal and aromatic plants and use of polyvalent processing plant (T. De Silva, M.A. Majid)
14.30 - 16.30 Visit to R&D institutions of INDENA (A. Bonati)
20.30 Dinner hosted by INDENA

26 March 1992

- 9.00 - 10.00 Continuation of presentation of and discussion on country papers (R. Andriantsiferana, H. Dadoun, A. Njikam)
10.00 - 10.45 Biological screening, product development and marketing aspects (B.N. Dhawan)
11.15 - 12.00 An overview of the approach adopted by the European industry and EEC for the evaluation and control of phytopharmaceuticals (A. Bonati)
12.00 - 13.00 Guidelines for assessment of herbal medicines - Regulatory needs for introduction of plant-derived medicine into the public health delivery system (O. Akerele)
14.30 - 18.00 Demonstration and discussion on practical aspects of processing technology - Visit to industrial unit (INDENA factory located in Settala, near Milan) (A. Bonati)

27 March 1992

- 9.00 - 10.15 Identification of technical co-operation, investment and joint venture projects
10.45 - 12.00 Finalization of conclusions and recommendations of the Workshop

LIST OF DOCUMENTS

Design options for a polyvalent pilot plant unit for the distillation and extraction of medicinal and aromatic plants, UNIDO, IPCT.143(SPEC.)

Guidelines for setting up data bases on medicinal plants (Y.R. Chadha, UNIDO Consultant)

Guidelines for the chemical and biological assessment of herbals and herbal preparations (A. Bonati, UNIDO consultant)

Issues in the integrated development of industrial utilization of medicinal and aromatic plants in developing countries (UNIDO)

WHO Guidelines for the assessment of herbal medicines (O. Akerele, WHO)

Production of phytopharmaceuticals - Assessment of flora, quality assurance, technology (E. Bombardelli, INDENA)

Methods for biological assessment of plant medicines (B.N. Dhawan)

Country papers:

The medicinal plant-based industry in Cameroon (A.P. Njikam)

Evaluation of Chinese drugs in the treatment of neoplastic diseases (Yan Sun)

The medicinal plant industry - An experience from Egypt (A.M. Molokhia)

The situation of the phytopharmaceutical industry in Guatemala (A. Saravia Gomez)

The development of traditional drugs in Indonesia (D. Hargono)

Pharmaceutical industry and medicinal plants in Korea (Chang Seung-Yeup)

Assessment of medicinal plants potential and research and development activities in Madagascar (R. Andriantsiferana)

Technologies for production of essential oils and medicinal plants, and marketing and export potential of aromatic plants in Madagascar (H. Dadoun)

Industrial utilization of medicinal and aromatic plants in Nigeria (M.M. Iwu)

Development of new drugs from indigenous plants and traditional remedies in Thailand (S. Wasuwat)

The potential of medicinal and aromatic plants in Turkey (H.C. Baser)

LIST OF PARTICIPANTS

Cameroon

Dr. Anthony P. Njikam, Director, Research and Development,
PATIENCE Pharmaceuticals, B.P. 2414, Douala
(UNDP fax 00237/224369)

People's Republic of China

Prof. Yan Sun, M.D., Chairman, Department of Medicinal Oncology,
Chinese Academy of Medical Sciences, P.O. Box 2258, Beijing
100021 (fax 00861/7713648)

Mr. Xinglin Deng, Consul, Consulate of the People's Republic of
China, Via Enrico Tazzoli 7, Milan, Italy

Egypt

Prof. Dr. Abdulla M. Molokhia, Director, Research & Development,
PHARCO Pharmaceuticals, P.O. Box 12, Sidi Gaber, Alexandria
(fax 00202/980730, telex 55480 pharc un)

Guatemala

Dra. Amarillis Saravia, Professor of Pharmacology, President of
the National Commission for Utilization of Medicinal Plants
(CONAPLAMED), Faculty of Chemistry and Pharmacy, University of
San Carlos of Guatemala, 5 Ave. 1-64, Zona 2, Guatemala 01002,
C.A. (UNDP fax 00502/2370304)

India

Dr. Bhola N. Dhawan, Director, Central Drug Research Institute,
Mahatma Gandhi Marg., Post Box No. 173, Lucknow 226 001
(fax 0091522/243405, telex 0535286)

Mr. Ravindra Yadilal Shah, Managing Partner, Uttam Corporation,
194, Khetwadi Main Road, Bombay 400004

Indonesia

Dr. Djoko Hargono, Director, Traditional Drugs Control
Directorate, Ministry of Health, Direktorat Pengawasan Obat
Tradisional, Jalan Percetakan Negara No. 23, Jakarta 10001
(UNDP fax 006221/3105251)

Dr. D. Sugiarto Sindoro, Association of Jamu Industry in
Indonesia, PT. Jamu Sido Muncul, Jl. Raya Kaligawe KM 4 LIK -
Tanah Makmur, Semarang (fax 580 332)

Italy

Mr. Guiseppe Battaglino, Official, Ministry of Health, Viale
Civiltà Romana 7, I-00166 Roma

Dr. E. Bombardelli, Chief Scientist, INDENA/Inverni della Beffa
Group, Via Ripamonti 99, 20141 Milan

Ing. D. Bonacorsi, Managing Director, INDENA/Inverni della Beffa
Group, Via Ripamonti 99, 20141 Milan

Dr. A. Bonati, Scientific Director, INDENA/Inverni della Beffa
Group, Via Ripamonti 99, 20141 Milan

Mr. V. Fachhetti, Fonctionnaire, Istituto per il Commercio Estero
(ICE), Corso Magenta 59, 20123 Milan

Mr. R. Pagliarin, Researcher, Dip. Chimica Organica, Università
di Milano, Via Venezian 21, Milan

Mr. G. Patri, Development Manager, INDENA/Inverni della Beffa
Group, Via Ripamonti 99, Milan

Korea

Mr. Chang Seung-Yeup, Assistant Section Chief in Specifications &
Analysis of Natural Product Sec., National Institute of Health,
5 Nokbun-Dong, Eunyung-Ku, Seoul 122-020 (fax 00822/3570532)

Madagascar

Prof. H. Dadoun, Chief Technical Adviser, UNDP/UNIDO, B.P. 1348,
Antananarivo (101) (UNDP fax 002612/33315)

Prof. R. Andriantsiferana, Directeur, Centre National de
Recherches Pharmaceutiques (CNRP), B.P. 702, Route d'Alarobia -
Analamahitsy, Antananarivo (101) (UNDP fax 002612/33315)

Nigeria

Prof. M.M. Iwu, Professor of Pharmacognosy, Faculty of
Pharmaceutical Sciences, University of Nigeria, Nsukka
(telex 51496 ulions ng)

Thailand

Dr. Sasithorn Wasuwat, Thailand Institute of Scientific and
Technological Research (TISTR), 196 Pahonyothin, Chatuchak,
Bangkhen, Bangkok (telex 21392 tistr th)

Turkey

Prof. Dr. K. Hüsnü can Baser, Professor of Pharmacognosy, Vice Dean, Faculty of Pharmacy, Anadolu University, 26470 Eskisehir (fax 009022/150127)

Mr. N. Özturanli, Medical Manager, Sanofi-Dogu Ilag, Yzb. Kaya Aldogan Sole, Kore Sohitten, Cad. No. 13, Zinarlikum, Istanbul

Mr. E. Sezik, Prof. of Pharmacognosy, Vice Dean, Gazi University, Eczacilik Fakultesi, 06330 Hipodrom, Ankara

World Health Organization (WHO)

Dr. Olayiwola Akerele, Programme Manager, Traditional Medicine, WHO, Palais des Nations, CH-1211 Geneva-27, Switzerland (fax 0502/27910746)

United Nations Industrial Development Organization (UNIDO)

Mr. T. De Silva, Special Technical Adviser, Chemical Industries Branch, Industrial Operations Technology Division, Department of Industrial Operations, P.O. Box 300, A-1400 Vienna, Austria (fax 222/232156)

Mr. M.A. Majid, Special Technical Adviser, System of Consultations Division, Department for Industrial Promotion, Consultations and Technology, P.O. Box 300, A-1400 Vienna, Austria (fax 222/237288)

Mr. S. Zampetti, Head, UNIDO Investment Promotion Service, Third Floor, Corso Magenta 59, I-20123 Milan, Italy (fax 0402/4985925)