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Expert Group Meeting on Medicinal
Plants and Other Issues - Pharmaceutical Industry
Vienna, Austria, 10-12 December 1986

REPORT *

prepared by
the UNIDO secretariat

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PREFACE

The Second General Conference of the United Nations Industrial Development Organization (UNIDO), held at Lima, Peru, in March 1975, recommended that UNIDO should include among its activities a system of continuing consultations between developed and developing countries with the object of raising the developing countries' share in world industrial output through increased international co-operation. In September 1975, the General Assembly endorsed the recommendation and requested UNIDO to implement it under the guidance of Industrial Development Board.

The Industrial Development Board decided to place the System of Consultations on permanent basis and it adopted the Rules of Procedure according to which the System of Consultations was to operate, including its principles, objectives and characteristics, notably:

- The System of Consultations shall be an instrument through which the United Nations Industrial Development Organization (UNIDO) is to serve as a forum for developed and developing countries in their contacts and consultations directed towards the industrialization of developing countries;

- The System of Consultations would also permit negotiations among interested parties at their request, at the same time as or after Consultations;

- Participants of each member country should include officials of Governments as well as representatives of industry, labour consumer groups and others, as deemed appropriate by each Government;

- Each Consultation meeting shall formulate a report, which shall include conclusions and recommendations agreed upon by consensus and also other significant views expressed during the discussions.

The First and Second Consultations on the Pharmaceutical Industry were convened in Estoril, Portugal, from 1 to 5 December 1980 and in Budapest, Hungary, from 21-25 November 1983, respectively. As a follow up action to the recommendations of the Second Consultation a meeting of experts related to work on Medicinal Plants and Other Issues was held in Vienna from 10-12 December 1986.

Organization of the meeting

1. The Expert Group Meeting on Medicinal Plants and Other Issues was opened by Mr. F.S. Souto, Deputy Director General, Department for Industrial Promotion, Consultation and Technology who welcomed the participants. In his address he drew the attention of the meeting towards the principal aim to review the work carried out on the ongoing issues related to the development of pharmaceutical industry in developing countries in general and on the issue of drugs based on medicinal plants in particular, and to evaluate the practical application of the same with a view to promote technical co-operation. He also invited the participants to make suggestions on aspects which are deemed essential for further discussion at the Third Consultation on

the Pharmaceutical Industry in order to accelerate the industrialization process in developing countries by creating a coherent national production system and providing pharmaceutical products that are essential to the immediate welfare of the population. He made reference to the agenda which included priority areas of various subsectors of the industry and drew the attention of the experts to highlighting possible new issues for consideration at the Third Consultation.

2. Mr. Gérard R. Latortue, Director of the System of Consultations, also addressed the participants stressing the importance of the Third Consultation on the Pharmaceutical Industry and in particular invited them to advise on any new issues to be taken up for further work by UNIDO. He emphasized the need for open discussion in reviewing the work of the secretariat by such highly professional experts. He said that the Third Consultation on the Pharmaceutical Industry would now be convened at the request of the host Government of Spain from 5-9 October 1987 in Madrid.

Mr. Souto and Mr. Latortue concluded their brief remarks by wishing to all participants a successful meeting and attainment of concrete results.

3. The UNIDO Secretariat explained the agenda for the meeting which covered the following topics:

- Data base for medicinal plants of therapeutic importance
- Steps for improved supply of medicinal plants
- Steps needed to meet regulatory standards
- Technology hardware package for handling of medicinal plants
- Genetic improvement of medicinal plants
- A case study - Applicability to the developing countries of Chinese model for factory made herbal medicine
- Directory of sources of supply
- Study on management skills for procurement
- Setting up of R+D Centre
- Experience related to multi-purpose plant for production of pharmaceutical chemicals
- Study related to industrial drug policies
- Model programme for production of biologicals
- Problems related to industrial financing
- Contractual arrangement for production of pharmaceuticals

4. Election of officers

Mr. S. Ramanathan was elected as Chairman for the meeting.

5. Discussions on subjects

The Secretariat made brief presentation on each of the topics mentioned above. This was followed by detailed and constructive discussions. The report was adopted at the last session of the meeting. The conclusions arising out of the discussions are detailed hereunder in para. 7.

6. The UNIDO Secretariat at the conclusion of the meeting thanked the participants for their active contributions to the meeting which will be reflected in the documents to be presented to the Consultation.

7. Conclusions and recommendations

I. Drugs based on Medicinal Plants

Data Base

Recognizing the magnitude of the work and resources required for the compilation of a comprehensive data base and for the retrieval of the information it contains, and realizing the fact that several independent data bases pertaining to this area have recently been established, it was recommended by the experts that:

- UNIDO should consider initiating work on the preparation of technical monographs on selected plants, giving all categories of information related to their industrial processing including technological aspects and methods for the assay of active ingredients.

- Member states in possession of pertinent information on plants of therapeutic importance should make such information available to UNIDO as well as the services of specialists for the preparation of monographs.

- UNIDO should also compile a list of already existing data bases having information relevant to the field of medicinal plants, together with the details of the aspects they cover.

Transfer of Technology for Genetic Improvement

The experts recommended that work be undertaken to identify the most important plant species for initiation of genetic improvement. It was suggested that the collaboration of pharmaceutical industry with UN organizations would be necessary.

The following steps should continue to be followed at national and international levels for the implementation of the work identified:

- Drawing up a list of the regions of maximum genetic diversity for selected plants and their near wild relatives. Collection and conservation and exchange of gene-pool material from these regions by linking national efforts, supplemented where necessary through international funding.

- Programming for the improvement of the selected plants by conventional and modern breeding techniques.

- Establishing national systems to ensure continuous flow of propagating material needed for the culture of medicinal plants as raw materials for industrial processing.

- Facilitating the production of nucleus breeders for the free flow of genetic stock and improved cultigens.

- Publishing of documents on available cultigens.

- Establishing liaison among organizations such as WHO, UNIDO, IAEA/FAO, IUCH, etc.

Steps needed to meet regulatory standards
Technology Hardware Package for medicinal plants industry

Reviewing the paper presented by the secretariat on pilot plant hardware package it was recommended by the experts that UNIDO may consider preparation of technical specifications for the pilot plant required by the medicinal-plant industry.

Efforts should be made by UNIDO to establish pilot plants in countries where such medicinal plants are abundant so that extracts could be made, active constituents can be isolated, and value-added products exported.

UNIDO should also assist developing countries by enhancing their awareness of regulatory standards and preparing information leaflets on procedures for isolation and assay of individual phytochemical constituents present in industrially utilizable medicinal plants.

Guidelines on Supply of Medicinal Plants as Raw Materials and Other Extracts

The experts were of the view that while the secretariat paper on this issue was useful, note also needed to be taken of the publication entitled "Guide to Good Agricultural Practices for Herbs" prepared by E.H.I.A. (European Herbal Infusion Association) which contains valuable supplementary information on the subject.

Factory produced Herbal Medicines - Chinese Model

The experts were of the opinion that the Chinese model based on development of drugs through industrial processing and clinical trials in the last 10-15 years may be applicable to certain developing countries where the necessary level of infrastructure is available. The transfer of technology based on this model to developing countries should be encouraged.

It was recognized that models based on other systems of traditional medicine may also be studied and their usefulness to other developing countries assessed.

II. Study to improve Management Skill for Procurement

The experts were of the view that the study was informative and useful. In this context it was mentioned that World Bank has plans to assist developing countries in procurement procedures and financing of pharmaceuticals.

III. R&D Centre for Information, Training and Development of Pharmaceutical Technology

The experts, while appreciating the need for the establishment of an R&D Centre under the auspices of UNIDO, expressed certain reservations about its feasible operations and suggested that the scope of its activities and its viable operation need further examination. The experts felt that the proposed Centre should concentrate in the first phase on training and development of technical and managerial skills in the pharmaceutical industry in developing countries, assisting in the transfer of technology to the least developed countries for the production of formulations and layout for pharmaceutical plants and exchange of information and promoting joint research activities in collaboration with other research institutes. The scope of the activities of the proposed Centre may be enlarged in the subsequent phases depending upon the experience gained.

It was further stressed that the activities of existing R&D Centres in developing countries should be strengthened and networks be established so that resources can be pooled for undertaking collaborative research in various areas of relevance to the pharmaceutical industry.

IV. Biologicals

The experts appreciated the paper on the model programme for the production of biologicals. There was agreement that due consideration be given to the humanitarian and other national aspects when examining the feasibility of establishing this industry. They stressed the need for regional production of vaccines and the efforts by the respective Governments as well as the UN agencies to initiate and materialize this programme.

V. Problems related to Industrial Financing

While discussing the issue the experts emphasized the need for additional work to be done in this area taking into account the information available in the countries and studies conducted by the World Bank, UNICEF and other organizations.

It was also stressed that Governments should consider granting loans on soft terms for the development of pharmaceutical industry on priority basis and providing protection to local industry through suitable tariff measures and fiscal policy.

The need for providing risk capital by Governments to developing countries' entrepreneurs wishing to set up new pharmaceutical plants that introduce new product or technology was emphasized.

VI. International Cooperation for the development of pharmaceutical industry - Exchange of experiences and information

While discussing the documents on international cooperation the experts appreciated the various steps already initiated by UNIDO for

promoting technical cooperation between developed and developing countries and amongst developing countries. It was felt that the time was opportune to enlarge the scope of international cooperation in the development of the pharmaceutical industry through a more active involvement at policy making and industry levels including representatives of professional industry associations, research institutes and others.

In particular the experts underlined the scope for cooperation in the following levels and areas:

- Enterprise to enterprise cooperation
- Training of personnel
- Exchange of experience at plant managers level
- Establishment of and promotion for joint research activities
- Preparation of directory of technological capabilities in developing countries
- Establishment of networks for exchange of data and information among developing countries.

The experts recommended that a paper for the consideration of the Third Consultation be prepared based on the above.

VII. Industrial Drugs Policies

The experts taking note of the paper on the factors having bearing on industrial drug policies emphasized the paramount need for the clear formulation of an industrial drug policy within the framework of national health and drug policy as a basic prerequisite for the promotion and establishment of the national pharmaceutical industry and the enactment of such legislation that may be required for implementing this policy.

It was also noted that WHO, while appreciating the work done by UNIDO in this regard, was proposing to formulate guidelines on the basis of "WHO Revised Drug Strategies" and within the framework of that organization's health policy programme on specific components of drug policies which would be of help to developing countries.

The experts highlighted the importance of follow up action on the conclusions of the study on industrial drug policies which are addressed to Governments, industry, medical practitioners, consumers and UN organizations.

VIII. Master Plan for Integrated Approach for the Development of Pharmaceutical Industry

The experts endorsed the views expressed by UNIDO regarding the need for preparation of a long-term master plan for the integrated development of pharmaceutical industry within the frame work of national health and drug policy keeping in view the socio-economic and health scenarios of each country.

IX. Contractual Arrangements for the Manufacture of Pharmaceuticals

The experts took note of the four new documents prepared by UNIDO and expressed their appreciation of the work done.

X. Development of Ancillary Industries

The experts advised that within the scope of integrated development of pharmaceutical industry UNIDO should take up on urgent basis as an issue the matter of the development and the establishment in developing countries of ancillary industries related to the pharmaceutical industry such as plastic and glass containers, other packaging materials and manufacture of machinery and equipment needed to meet the requirements of the pharmaceutical industry within the country or on a regional basis.

They emphasized the need to elaborate on these two items in the preparatory work for the Third Consultation for consideration as new issues for UNIDO's activities in its future programme.

Expert Group Meeting on
Medicinal Plants and Other Issues

APPENDIX I

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