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UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org

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Third Consultation on the
Pharmaceutical Industry

Madrid, Spain, 5-9 October 1987

PROGRESS REPORT ON ACTIVITIES RELATED TO CONSULTATIONS ON THE PHARMACEUTICAL INDUSTRY

Background Paper

Prepared by

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. 1/

At its seventh special session, the General Assembly, in its resolution 3362(S-VII), invited the Industrial Development Board to draw up the rules of procedure according to which the UNIDO System of Consultations would operate. At its sixteenth session, the Industrial Development Board adopted the Report of the Permanent Committee on the work of its sixteenth session, including the rules of procedure for the System of Consultation. 2/

The UNIDO System of Consultations is a forum for identifying problems associated with the industrialization of developing countries, for considering ways and means to accelerate their industrialization and for contributing to closer industrial co-operation among member countries, in accordance with the Lima Declaration and Plan of Action. 3/

The First and Second Consultations on the Pharmaceutical Industry were convened at Lisbon, Portugal, from 1 to 5 December 1980, and at Budapest, Hungary, from 21 to 25 November 1983, respectively.

The Third Consultation on the Pharmaceutical Industry is being convened at Madrid, Spain, from 5 to 9 October 1987.

1/ Report of the Second General Conference of the United Nations Industrial Development Organization (ID/CONF.3/31), chap. IV, "The Lima Declaration and Plan of Action on Industrial Development and Co-operation", para. 66.

2/ The System of Consultations, (PI/84).

3/ Ibid., paras. 1 and 4.

Introduction

This progress report presents an overview of the UNIDO Consultations on the Pharmaceutical Industry from inception to date.

Chapter I gives the background on how the issues for discussion at the First Consultation were selected; a short resume of the issues discussed and the conclusions and recommendations of the First Consultation; and a short account of the follow-up action taken to implement the recommendations of the First Consultation, including a chronology of activities, expert group meetings and substantive developments for each issue.

Chapter II gives the background on the identification of new issues for the Second Consultation, the issues presented for discussion and the conclusions and recommendations of the Second Consultation. It also presents the follow-up actions taken to implement the recommendations of the Second Consultation, including a chronology of activities, expert group meetings and substantive developments for each issue.

Chapter III shows the issues being presented for discussion at the Third Consultation, including a brief description of foci for discussion.

The annexes provide relevant information on provisional agenda, a list of documents and technical assistance projects in pharmaceuticals.

To facilitate the participants' preparations for the Third Consultation, the following types of documents have been prepared:

(a) Issue papers, which provide the substantive essentials of the issue under consideration and the questions derived from it that require discussion and/or recommendations for action;

(b) Background papers, which give the detailed substantive justification for the issue under discussion and/or the detailed events, discussions and recommendations of the expert group meetings related to the implementation of the issue;

(c) Information or reference papers, which include studies, field surveys, industrial profiles and other documents.

Each paper is self-contained as far as practicable; thus, participants will not have to resort to other papers for information.

I. FIRST CONSULTATION ON THE PHARMACEUTICAL INDUSTRY

A. Selection of issues for the First Consultation: convening of panels of experts and interregional and global preparatory meetings

In order to identify issues suitable for Consultations on the pharmaceutical industry, UNIDO convened two meetings of panels of experts in July 1977 and March 1978, respectively, with participants from developed and developing countries. Thereafter, an Interregional Meeting of Experts from developing countries was convened at Cairo, Egypt, in January 1979, with observers from the industry. Sixteen topics were presented by UNIDO that could be chosen as issues for consideration at the First Consultation. The above-mentioned meetings identified the priority issues for consideration at the First Consultation on the Pharmaceutical Industry, keeping in view the need to develop the pharmaceutical industry in developing countries and to deal with the constraints impeding its progress.

The following three issues were chosen for presentation at the First Consultation:

Issue I. Pricing and availability of intermediates and bulk drugs (pharmaceutical chemicals)

Issue II. Contractual arrangements for the production of drugs, covering two parts:

(a) Relevant issues to be taken into account when negotiating a transfer of technology agreement;

(b) Preparation of guidelines for licensing arrangements for the transfer of technology to manufacture essential drugs and formulations.

Issue III. Availability, terms and conditions for the transfer of technology for the manufacture of essential drugs included in the UNIDO illustrative list.

The First Consultation on the Pharmaceutical Industry was held at Lisbon, Portugal, in December 1980, and was attended by 195 participants from 67 countries and representatives from 13 international organizations.

The Consultation decided to discuss issue I in the plenary, while issues II and III were discussed in two working groups.

B. Conclusions and recommendations of the First Consultation

The Consultation adopted a set of conclusions and recommendations, 4/ which can be summarized as follows:

(a) UNIDO should set up a committee of experts on pharmaceuticals from developed and developing countries to ascertain the technical and economic aspects of the availability of intermediates and bulk drugs (pharmaceutical chemicals);

(b) UNIDO, in co-operation with an ad hoc panel of experts, should prepare a document listing the various terms and conditions that could be incorporated in contractual arrangements for the production of drugs;

4/ Report of the First Consultation on the Pharmaceutical Industry, (ID/259), pp. 1-7.

(c) With respect to the 26 essential drugs identified by UNIDO, transfer of technology on mutually acceptable terms should be facilitated by the provision of relevant reference information to be compiled by UNIDO covering technical aspects (e.g. production level, magnitude of investment, infrastructure etc.) in order to help developing countries in bilateral negotiations on technology transfer.

C. Actions taken to implement the recommendations of the First Consultation

As a follow-up action on the recommendations of the First Consultation, UNIDO undertook two activities in parallel during 1981:

(a) It convened a round table meeting of experts to advise UNIDO on the actions to be taken to implement the recommendations of the First Consultation, including the composition of committee of experts to deal with issue I and an ad hoc panel of experts to deal with issue II;

(b) It carried out a survey on the transfer of technology to facilitate the implementation of issue III.

The recommendations of the expert group meetings laid the course for the implementation of the recommendations of the First Consultation on various issues. The round table meeting on the development of the pharmaceutical industry convened in Morocco in December 1981 recommended that the UNIDO committee of experts on pharmaceuticals, in the context of issue I, should pay particular attention to those bulk drugs (pharmaceutical chemicals) and their intermediates for which there are limited sources of supply and that the committee should include representatives of manufacturers of such pharmaceutical chemicals. UNIDO should update the directory of sources of supply periodically. It also recommended guidelines and main principles to be considered in the preparation of documents on contractual arrangements as well as items to be included in such arrangements. It defined the scope of study on relevant topics to be taken into account when negotiating transfer of technology agreements.

Following the advice of the round-table meeting, the meeting of the committee of experts on pharmaceuticals was convened in October 1982 in Paris, France, and the meetings of the ad hoc panel of experts on contractual arrangements was convened twice at Vienna in December 1982 and April 1983, respectively. A meeting on co-operation among developing countries was convened in September 1983 at Tunis, Tunisia.

Issue I - Availability and pricing of pharmaceutical chemicals and their intermediates

The committee of experts on pharmaceuticals took note of the factors affecting the development of the pharmaceutical industry, including the existing disparity between prices of pharmaceutical chemicals and their intermediates, the constraint imposed by the prices of intermediates on the production of pharmaceutical chemicals and the non-availability of technology for production in developing countries. The committee's recommendations on this issue pointed out two alternative solutions to the supply of pharmaceutical chemicals and intermediates to assist developing countries:

(a) The production of pharmaceutical chemicals and intermediates in developed countries to meet collective requirements of interested developing countries;

(b) The production of pharmaceutical chemicals and intermediates in developing countries through the transfer of technology, a route that also effectively covers the solution to issue III as well.

To facilitate the implementation of alternative (a) above, UNIDO sent out a questionnaire to ascertain the needs of developing countries for pharmaceutical chemicals and intermediates. Some countries that replied expressed reservations about the lack of information on sources of supply, criteria for purchases, especially regarding tied loans, while other countries stated that this ascertainment contradicts the spirit of transfer of technology.

On the basis of replies to a questionnaire on sources of supply and other available information, UNIDO compiled a directory of sources of supply for 26 essential pharmaceutical chemicals and their intermediates. Alternative (b) above is covered under issue III.

Issue II - Contractual arrangements for the production of drugs

In accordance with the recommendations of the First Consultation and in line with the advice of the round table meeting, the ad hoc panel of experts on contractual arrangements in the pharmaceutical industry, at its 1982 and 1983 meetings, completed the revision of documents "Contractual arrangements for the transfer of technology for the manufacture of bulk drugs/intermediates included in UNIDO's list" (ID/WG.393/1), "Contractual arrangements for the transfer of technology for the formulation of dosage forms" (ID/WG.393/3) and "The setting up of a plant for the production of bulk drugs/intermediates included in UNIDO's list" (ID/WG.393/4). The panel recommended that these three revised documents should be presented to the Second Consultation.

In addition, the ad hoc panel recommended that UNIDO should present to the Second Consultation a proposal for the preparation of the following additional documents: 5/

(a) Items that could be included in turnkey contractual arrangements for the setting up of a plant for the production of bulk drugs/intermediates included in the UNIDO list;

(b) Arrangements for technical assistance for the formulation of pharmaceutical forms.

Issue III - Transfer of technology for the manufacture of essential drugs included in the UNIDO illustrative list

Although the First Consultation only gave general recommendations on issue III, the committee of experts that discussed issue I pointed out that the problem of price and availability of bulk drugs and intermediates could be solved through their local production in developing countries, which in turn requires transfer of technology.

In order to prepare the study on the subject as recommended by the committee, a questionnaire was sent to 130 major pharmaceutical producers and organizations in developed and developing countries. Only 14 positive replies

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5/ See ID/WG.393/7 for full information.

were received, covering 16 drugs and 12 intermediates. Furthermore, while20 technology holders expressed regret, some other companies requested that the information they supplied should be treated as confidential and thus should not be published.

Despite the disappointing outcome and considering the intention of the committee to solve this issue through production in developing countries, efforts were continued, and eventually some independent research-based technology holders were identified that were willing to transfer technology for large number of drugs. 6/

To complement the action referred to above, UNIDO simultaneously undertook the study of technical, economic and environmental aspects related to transfer of technology and the development of the pharmaceutical industry. These studies included: technical profiles for production of pharmaceutical formulations; case studies on national drug policies of four selected developing and developed countries, indicating the impact of such policies and pricing mechanism in the development of the pharmaceutical industry; environmental aspects, in particular water use and effluents related to the establishment of manufacturing facilities; strengthening of the study on relevant topics to be taken into account in the preparatory phase of technology transfer agreements for the production of pharmaceuticals; a summary of industrial property protection on pharmaceuticals in developing countries; and a study on prospects for the production of vaccines and other immunological agents in the developing countries.

II. SECOND CONSULTATION ON THE PHARMACEUTICAL INDUSTRY

A. Issues for the Second Consultation: ongoing and new issues

Two ongoing and two new issues were identified for presentation to the Second Consultation.

The ongoing issues included:

(a) Contractual arrangements for the production of drugs;

(b) The availability, pricing and transfer of technology for the production of drugs.

The availability and pricing of pharmaceutical chemicals and their intermediates (issue I) and the issue related to transfer of technology (issue III) of the First Consultation were merged as one issue for subsequent discussions and implementation. This was in line with the recommendations made by the committee of experts on pharmaceuticals, which recommended that a solution to these problems should be found through the transfer of technology for the production of pharmaceutical chemicals and their intermediates in the developing countries.

The new issues identified for discussion at the Second Consultation, based on the recommendations of the expert group meetings (see chapter I, section A, above) were medicinal plants and immunologicals.

6/ See ID/WG.393/9 for full information.

The issue on the development of drugs based on medicinal plants 7/ laid emphasis on the need to complement expensive chemical drugs with those based on medicinal plants to provide wide health care coverage. It highlighted the need for assistance to increase the supply of medicinal plants as a raw material, to improve their economic return and to upgrade production from crude plant extracts to pure active principles.

The issue of biologicals 7/ highlighted the urgent need for the production of vaccines in developing countries, since infectious diseases remained one of the greatest problems to be tackled by the developing countries.

The Second Consultation, which was held at Budapest, Hungary, in November 1983, was attended by 215 participants from 66 countries and by 18 observers from 12 international organizations.

The Consultation decided to discuss the issues in two working groups. The issue related to contractual arrangements was discussed in the first group, while the issues relating to availability, pricing and transfer of technology, medicinal plants and biologicals were discussed in the second group.

B. Conclusions and recommendations of the Second Consultation

The Consultation adopted a set of conclusions and recommendations which can be summarized as follows: 8/

(a) UNIDO, in co-operation with the ad hoc panel of experts, should finalize the three documents on contractual arrangements for the production of drugs and thereafter disseminate them widely. UNIDO should also prepare new documents on contractual arrangements for turnkey arrangements and technical assistance;

(b) UNIDO should recirculate a simplified questionnaire on the transfer of technology and prepare feasibility studies at the request of interested countries. UNIDO should expand the "Directory of sources of supply" to cover in full the WHO model list of essential drugs and should periodically update it. UNIDO was requested: (i) to prepare a study on improving management skill on procurement; (ii) to prepare a study on factors having bearing on industrial drug policies (based on studies made by United Nations agencies); and (iii) to undertake a feasibility study and steps towards establishing a process research and development centre;

(c) UNIDO was further requested to initiate the compilation of a data base for medicinal plants, to outline steps on the transfer of technology for the genetic improvement of medicinal plants, to develop guidelines to improve the supply of medicinal plants as raw material or processed product and to play intermediary role in the transfer of technology;

(d) The adoption of a step-by-step approach for establishing control and production facilities for the production of biologicals, implementing technical assistance and support programmes and promoting transfer of technology.

7/ Background documents ID/WG.393/10 and ID/WG.393/13 Rev.1.

8/ See the report of the Second Consultation (ID/311) for details.

C. Action taken to implement the recommendations of the Second Consultation

The activities of UNIDO as a follow-up to the recommendations of the Second Consultation are described below.

Issue 1: Contractual arrangements for the production of drugs (pharmaceutical chemicals, their intermediates and pharmaceutical formulations)

UNIDO convened the third meeting of the ad hoc panel on contractual arrangements in April 1985. The panel, in the light of comments and statements made at the Second Consultation, finalized the following documents, which were also widely disseminated:

(a) Items that could be incorporated in contractual arrangements for the transfer of technology for the manufacture of those bulk drugs/intermediates included in the UNIDO illustrative list (ID/WG.393/1/Rev.2);

(b) Items that could be included in contractual arrangements for the transfer of technology for the formulation of pharmaceutical dosage forms (ID/WG.393/3/Rev.2);

(c) Items that could be included in contractual arrangements for the setting up of a plant for the production of bulk drugs (or intermediates) included in the UNIDO illustrative list (ID/WG.393/4/Rev.2).

It was emphasized at the panel's meeting that these documents would be of immense benefit to users in developing countries and would assist, in North-South and South-South dialogue, in international co-operation for the development of the pharmaceutical industry.

UNIDO has also prepared, in co-operation with the ad hoc panel, a reference paper on areas not covered by the three documents referred to above.

In addition, the third meeting of the ad hoc panel was able to complete a review of the outline of the three new documents entitled:

(a) Items that could be included in contractual arrangements for the setting up of a turnkey plant for the formulation of pharmaceutical forms;

(b) Items that could be included in contractual arrangements for the setting up of a turnkey plant for the production of bulk drugs (or intermediates) included in the UNIDO list;

(c) Items that could be included in contractual arrangements for technical assistance for the formulation of pharmaceutical forms.

A fourth meeting of the ad hoc panel could not be convened in 1986; instead, the panel members were requested to provide written comments on the draft documents.

The documents have been finalized by UNIDO, taking into account the comments received from the members of the ad hoc panel, and is presented to the Third Consultation to approve their dissemination by UNIDO to interested parties in developed and developing countries.

The six documents referred to above reflect more realistic balance between the interest of parties in an agreement and may be used by interested parties as an aid in negotiation of contracts. Regional workshops on the subject may serve to: promote the exchange of experience in negotiating contractual arrangements, assist government officials and industry managers, enterpreuneurs to negotiate at equal footing with the experienced technology suppliers, upgrade industrial contract drafting abilities by exposure to the current international practices etc. and also assist UNIDO in further work, if needed to be done in the contractual documents.

Issue II: Availability, pricing and transfer of technology for pharmaceutical chemicals and their intermediates

There has not been any ready-made formula to resolve the problems associated with this issue. In implementing the recommendations of the Second Consultation as far as is permissible within its resources, UNIDO has prepared a number of studies and carried out surveys on sources of supply for pharmaceutical chemicals and intermediates and on the availability of technology. On the transfer of technology, two questionnaires, one addressed to transferors and a second to recipients of technology for pharmaceutical chemicals, intermediates and formulations, were sent to over 250 pharmaceutical producers and organizations in developed and developing countries. Positive responses from transferors of technology from both developed and developing countries included information from 43 organizations for pharmaceutical formulations, 61 organizations for pharmaceutical chemicals and 19 for intermediates. Similarly, the responses from prospective recipients of technology included information from 29 organizations for pharmaceutical formulations, 36 for pharmaceutical chemicals and 8 for intermediates. UNIDO has endeavoured to put technology recipients in contact with the technology holders and has assisted in providing technical assistance and, in few cases, in conducting feasibility studies leading to integrated development of the pharmaceutical industry and transfer of technology for the production of pharmaceutical chemicals.

UNIDO efforts in relation to this issue include the preparation of documents and complementary actions covering:

(a) An enlarged directory of sources of supply for pharmaceutical chemicals and their intermediates, covering 100 essential drugs included in WHO model list of essential drugs;

(b) A study to assist developing countries to improve management skill for the procurement of pharmaceuticals;

(c) A study based on work done by United Nations agencies related to factors that have a bearing on the industrial drug policy and consequently on the development of a domestic pharmaceutical industry;

(d) Revised technical profiles for the establishment of pharmaceutical formulation units in developing countries;

(e) A survey on the transfer of technology and a study covering a master plan for an integrated development of the pharmaceutical industry and a document with special emphasis on the application of multi-purpose plant;

(f) To complement efforts for domestic production, a set of studies were prepared covering technical and economic analysis of the manufacture of four selected pharmaceutical chemicals: chloroquine phosphate (UNIDO/IS.518), isoniazid (UNIDO/IS.622), ethambutol (UNIDO/IS.588) and acetyl salicylic acid;

(g) Arrangements towards the establishment of a process research and development centre for pharmaceuticals

Steps in the direction of convening on regular basis joint WHO, UNICEF, UNCTAD, UNIDO workshops in collaboration with interested organisations on procurement would facilitate resolving problems related to availability and pricing aspects. The multipurpose plant concept for pharmaceutical chemicals and establishment of research and development Centre for information, training and development of technology would be result oriented steps in resolving the technology problems. Pooling of resources and efforts by the United Nations agencies would go long way in assisting the developing countries. The results of jointly planned exercises can be evaluated after a lapse of three to five years.

Issue III: The development of drugs based on medicinal plants

UNIDO convened an informal meeting of experts on medicinal plants in February 1985 to discuss the activities that were undertaken on the implementation of the recommendations of the Second Consultation related to the issue. The following actions were undertaken:

(a) The compilation of a data base on medicinal plants was found to be a very involved task. However, to initiate the work on the data base, information on five medicinal plants of known therapeutic importance has been collated. The information relates to botanical, ethnomedical, chemical, pharmacological, agrotechnological, technology and market aspects;

(b) In addition documents on transfer of technology for the genetic improvement of medicinal plants, guidelines to improve the supply of medicinal plants as a raw material or as processed products were prepared;

(c) The UNIDO technical assistance programme to developing countries was further intensified.

Issue IV: Biologicals

UNIDO established an Advisory Panel on Preventive Medicine to receive sustained professional advice and guidance at the highest level in the area of preventive medicine, more specifically to implement a programme on the Industrial Production of Biologicals (IPB). Since the Second Consultation on the Pharmaceutical Industry, the Panel has held four meetings and provided guidance on the implementation of the recommendations of the Second Consultation and on the execution of technical assistance programmes.

A basic document on techno-economic aspects of industrial production of biologicals has been prepared by UNIDO (Model programme for production of vaccines, IO.2). The implementation of the Model Programme for Vaccine Production was initiated by the establishment of a pilot demonstration unit in Cameroon. UNIDO is also responding positively to requests for the rehabilitation or expansion of existing production and control facilities in Africa, coupled with discussion with other United Nations agencies, such as WHO and the United Nations Children Fund (UNICEF), and bilateral aid organizations on the priority need for assured utilization of domestically manufactured biologicals.

The overall production capacities in developing countries need evaluation and consideration as regard the installation of new facilities for both human and veterinary vaccines thus sharing the common services as far as possible to economise on the overall investment. UNIDO competence and experience is available in developing local production and these services are also available to other relevant agencies for co-operation.

In order to promote the production of blood derivatives, sera and vaccines, UNIDO convened meetings at the regional level in 1984 (Latin America) and 1986 (Asia) and plan to hold one in 1987 (Africa).

The Advisory Panel has recommended that UNIDO should prepare a series of documents, including the following:

Transfer of technology for biological production

Production of BCG vaccines (surface cultivation)

Production of oral poliomyelitis vaccine (Sabin)

Directory of potential partners for transfer of technology for biological production

Furthermore, based on recommendations of the Panel, a sub-account of the United Nations Industrial Development Fund (UNIDF) has been established in UNIDO to finance the implementation of the IPB programme.

D. Additional activities related to the pharmaceutical sector

UNIDO has pioneered in setting up the International Centre for Genetic Engineering and Biotechnology, with a component each in Italy and India. Among other applications of biotechnology and genetic engineering, the activities cover work on the pharmaceutical sector. UNIDO co-operates on programmes related to:

(a) The organization of training in specialized topics;
(b) Promotional activities for bringing results of R+D to pilot scale;
(c) Planning and operation of affiliated centres and network;
(d) The dissemination of processes and expertise developed at the Centre.

To create a sound technical basis related to pharmaceutical sector, UNIDO has prepared additional studies that provide data and information for analysing the sector and identifying new issues. The studies covering substantive information include:

(a) Strategies and policies for the development of domestic pharmaceutical industry;

(b) Assessment of industrial and marketing aspects of factory-produced herbal medicine - A case study of Chinese experience;

(c) Problem of industrial financing related to the pharmaceutical sector in developing countries;

(d) Women and industrialization - A case study on the employment and training practices concerning women in the pharmaceutical industry in Puerto Rico.

E. General remarks

The Consultation may consider that the activities initiated or completed on these issues - some of which are of a continuous nature, such as the updating of directory on sources of supply of pharmaceutical chemicals and intermediates, information on technology and the technical co-operation activities - have been sufficient and that no additional action is needed. Nevertheless, some of the conclusions on these issues, as reflected in the relevant background papers, would seem to require the guidance of the Third Consultation regarding further action.

III. IDENTIFICATION OF NEW ISSUES

UNIDO covened a meeting of experts in December 1986 on medicinal plants and other issues related to the development of the pharmaceutical industry in developing countries. The meeting reviewed the progress of work for the Third Consultation, and, in the light of this and the experts' estimate of priority areas, two new issues were identified by the experts for discussion at the Consultation. These included:

(a) Industrial utilization of medicinal plants with emphasis on three main topics:

(i) Factory-produced herbal medicine;
(ii) Technology for the genetic improvement of medicinal plants;
(iii) Process technology development - technology hardware package and product standardization;

(b) International co-operation for the development of pharmaceutical industry, with special reference to:

(i) Exchange of information and experience;
(ii) Integrated approach to development of pharmaceutical industry;
(iii) Development of pharmaceutical related ancillary industries, with special reference to packaging materials.

Brief information and references to background documentation relevant to those issues are presented below.

A. Industrial utilization of medicinal plants

The importance of medicinal plants as a source of drugs contributing to health care programmes and economies of developing countries is well established. There is a need for the systematic utilization and development of plant resources and for technology to upgrade the cultivation and production of plant-derived pharmaceuticals. Background documents prepared for the Consultation on this subject (as well as discussion and conclusions of the Expert Group Meeting) mentioned above highlight the main topics to be included in this issue, which are discussed below.

Factory-produced herbal medicine

Traditional herbs and medicinal plants are widely grown, produced and used in developing countries. They are also a source of important export earning. The most immediate objective in this field is to transform this type of traditional products into scientific formulation, which could be prescribed by and administered according to accepted professional practice. Further, there is also a need to apply modern scientific procedures for the extraction of active principles and develop and register marketable, safe, efficacious and stable formulations. Thus, these plants could serve as a raw-material base for the emergence of a modern industry that is based on sound scientific principles and could serve as an example to be adapted for use in many developing countries. Methodology from cultivation to processing, clinical trials and dispensing is available. The case study of factory produced herbal medicine in China may be of interest to developing countries where the necessary level of infrastructure is available.

Technology for genetic improvement of medicinal plants

There is a need to improve the cultivation of medicinal plants in order to arrive at maximum standardized contents, stabilized supplies and improved economic return. The best approach to achieve these goals would be to work on the genetic improvement of medicinal plant species through conventional as well as new techniques. The establishment of international co-operation on the transfer of technology for genetic improvement, the exchange of know-how, the storage of genes and their availability to developing countries would help this process.

Industrial utilization of medicinal plants - process technology development and product standardization

Given the fact that considerable research has already been carried out on the phytochemical constituents of medicinal plants that are indigenous to several developing countries, there is a need for capitalizing on the results of this research. The expectations are to develop standardized, safe and stable preparations from medicinal plants for primary health care use. This is best served by enabling the developing countries to have access to suitable pilot-scale facilities for technology development and adaptation.

It is considered that a model versatile pilot plant could be designed to serve such a purpose and would have the advantage that it could be constructed and installed relatively cheaply in selected developing countries where the appropriate capabilities are available.

In addition to pilot plant facilities, however, developing countries should have the benefit of modern analytical instrumentation. This is necessary to provide the basis for quality assessment to ensure compliance with regulatory standards and procedures for isolation, separation and assay in the case of products developed.

B. International co-operation

Since the Second Consultation, the need has been increasingly felt for greater availability and exchange of information, know-how and experience between developed and developing countries as well as between developing countries themselves in the pharmaceutical industry at both the policy-making level and the enterprise level.

At the policy-making level, linking national economic, health and drugs policies has obvious advantages owing to the special need that the pharmaceutical industry serves, with all its economic and social ramifications, in every country. Among the background papers prepared in this field are the master plan for an integrated approach for the development of the pharmaceutical industry and the national industrial drug policy in developing countries as well as the development of the pharmaceutical ancillary industries, with special reference to packaging materials, the multipurpose pilot plant for production of pharmaceutical chemicals on national level and the model programme for the production of biologicals. It is clear that the establishment of a successful national pharmaceutical industry would have to look at this issue with a view of ensuring the health of the population, providing the industry with the scientific and managerial infrastructure for its success, the provision of raw materials and intermediates and other physical inputs needed to sustain production and the required policy incentives to allow its growth. Experiences of various countries vary according to the socio-economic system and levels of development, and there is a continuous need to exchange experience, information and know-how to mutually enrich the functioning of this exercise. The establishment, on co-operative basis, of a research and development centre for information, training and development of pharmaceutical technology is considered to be a positive step.

At the enterprise levels, the need to exchange information, experience and know-how on production, research and development, marketing, prices, availability of technology, training etc. at the national, subregional, regional and global levels is increasing ever more with increased diversity of development models, new fields of medicine and drugs and the application of new production and management methods.

In addition to this report and the Aide-Memoire to the Third Consultation, participants are invited to take note of the information referred below and annotated in the annexes. Furthermore the information provided in the offer/request for technical assistance/investment provided in the Aide-Memoire will offer additional opportunity to identify technical assistance projects. It is hoped that participants at this consultation would take full benefit of documents presented in their deliberations and to arrive at mutually beneficial conclusions and recommendations as well as agreement on bilateral assistance.

Provisional agenda for the Consultation (annex I);

List of documents (annex II);

UNIDO technical assistance projects in pharmaceuticals (annex III).

Annex I

PROVISIONAL AGENDA

1. Opening of Consultation

2. Election of Chairman, Vice-Chairmen and Rapporteur

3. Adoption of agenda

4. Progress report on the activities related to Consultations

5. Presentation of the issues by the Secretariat:

   Issue I. Industrial utilization of medicinal plants:

   - Factory-made herbal medicine
   - Technology for genetic improvement
   - Process technology development - products standardization

   Issue II. International co-operation for the development of the pharmaceutical industry:

   - Exchange of information and experience
   - Master plan for the development of the pharmaceutical industry
   - Development of pharmaceutical-related ancillary industries, with special reference to packaging materials

6. Discussion of the issues

7. Conclusions and recommendations

8. Adoption of report

9. Closing of Consultation

10. Negotiation on industrial investments - technical co-operation projects

Annex II

PROVISIONAL LIST OF DOCUMENTS

Background papers

- Progress report on activities related to Consultations on the pharmaceutical industry
- Availability, pricing and transfer of technology for pharmaceutical chemicals and their intermediates (ID/WG.466/8, SPEC)
- Directory of sources of supply of pharmaceutical chemicals, intermediates, some raw materials and biologicals - based on WHO model list of essential drugs (ID/WG.466/1, SPEC)
- Study to assist in improving management skill for procurement
- Factors having a bearing on industrial drug policies (ID/WG.466/6, SPEC)
- Multipurpose pilot plant for the production of pharmaceutical chemicals (ID/WG.466/7, SPEC)
- Guidelines to accomplish the improved supply of medicinal plants as raw materials or processed products
- The industrial utilization of medicinal plants within developing countries:
  - Process technology development and product standardization (ID/WG.466/14, SPEC)
  - Transfer of technology for the genetic improvement (ID/WG.466/13, SPEC)
  - Factory-produced herbal medicine - Chinese model
- The challenge of biological technology transfer to developing countries (ID/WG.466/10, SPEC)
- International co-operation in the development of pharmaceutical industry - with specific reference to:
  - Exchange of information and experience (ID/WG.466/15, SPEC)
  - Master plan for the development of an integrated pharmaceutical industry (ID/WG.466/16, SPEC)
  - Development of the pharmaceuticals related ancillary industries in developing countries, with special reference to packaging materials (ID/WG.466/17, SPEC)

Reference papers

- Women in the pharmaceutical sector - a case study of the experience of Puerto Rico - a summary (ID/WG.466/12, SPEC)
- Problems associated with industrial financing related to the pharmaceutical sector

- Establishment of a research and development centre for pharmaceuticals

- Review of work on contractual arrangements for the production of pharmaceutical chemicals, their intermediates and formulations (ID/WG.466/9, SPEC)

- Items which could be included in contractual arrangements for the setting up of a turnkey plant for the production of pharmaceutical dosage forms (ID/WG.466/2, SPEC)

- Items which could be included in contractual arrangements for the setting up of a turnkey plant for the production of bulk drugs (pharmaceutical chemicals) or intermediates included in UNIDO list (ID/WG.466/3, SPEC)

- Items which could be included in contractual arrangements for technical assistance for the formulation of pharmaceutical dosage forms (ID/WG.466/4, SPEC)

- Contractual arrangements for the production of pharmaceutical chemicals or intermediates and pharmaceutical formulations (Additional clauses for previous documents), (ID/WG.466/5, SPEC)

- Data base for medicinal plants (ID/WG.466/11, SPEC)

- Model programme for the production of vaccines in developing countries (IO/2)

- New approaches to vaccine development - World Health Organization

- Report of expert group meeting on medicinal plants and other issues - pharmaceutical industry (IPCT 20, SPEC)

Issue Papers

Issue I: Industrial utilization of medicinal plants

- Process technology development and products standardization
- Transfer of technology for the genetic improvement of medicinal plants
- Factory-produced herbal medicine

Issue 2: International co-operation in development of pharmaceutical industry, with specific reference to:

- Exchange of information and experience
- Master plan for integrated development of the pharmaceutical industry
- Development of the pharmaceutical-related ancillary industries in developing countries, with special reference to packaging materials

ANNEX III

List of technical assistance

On-going technical assistance projects - 1987

	Country	Title
1.	Burkina-Faso	Assistance in the production of pharmaceuticals from selected medicinal plants.
2.	Cuba	Development of technologies for the production of steroids.
3.	Iran	Transfer of technology for the production of Pharmaceutical Chemicals in a multi-purpose pilot plant.
4.	Mongolia	Assistance to production of bioactive materials (enzymes, hormones, etc...) from animal by-products.
5.	Mongolia	Transfer of technology for production of blood derivatives.
6.	Mongolia	Establishment of a modern tabletting unit.
7.	Nepal	Assistance to maximize the utilization of capacities at Royal Drugs Limited.
8.	Nepal	Processing of medicinal plants cultivated in Nepal.
9.	Rwanda	Establishment of a production unit for pharmaceutical preparations based on medicinal plants.
10.	Republic of Korea	Screening centre for pharmaceuticals leading to discovery of new drugs.
11.	SADDC countries	Preparation of a programme for the local production of veterinary drugs and vaccines.
12.	Tanzania	Assistance in the establishment of a pharmaceutical production unit in Zanzibar.
13.	Turkey	Production of pharmaceutical materials from medicinal plants.
14.	Tanzania	Assistance for the production of plant derived pharmaceuticals.
15.	L'Union Monétaire Ouest Africaine (UMOA)	General investment opportunity study on the development of pharmaceutical industry in UMOA countries.

Projects finalized furing 1984/1986

	Country	Title
1.	Algeria	Establishment of a development plan for an integrated pharmaceutical industry for 1985-1005.
2.	Cuba	Transfer of technology for the production bulk synthetic drugs in a multi-purpose plant.
3.	Guinea	Rehabilitation and establishment of a unit for the production of medicaments.
4.	(Global)	Preparation of a model programme for the production of vaccines in developing countries.
5.	India	Modernization of facilities for the manufacture of anti-malarial drugs.
6.	India	Upgrading of technology in India for the extraction of alkaloids from opium.
7.	Morocco	Investigation of possibilities for the local production of bulk synthetic drugs.
8.	Mozambique	Establishment of facilities for the production of oral rehydration salts.
9.	Mali	Creation of a decentralization production unit for essential drugs and plant-derived pharmaceuticals.
10.	Nicaragua	Assistance in the development of the pharmaceutical sector.
11.	Regional Africa	A survey on the production of vaccines in Africa.
12.	Regional Asia	A survey on the production of biologicals in ASEAN countries.
13.	Venezuela	Preparation of a proposal for local production of pharmaceutical chemicals.
14.	Zimbabwe	Investigation of possibilities for the local production of bulk synthetic drugs.

Technical assistance project to be implemented in 1988 and onwards

	Country	Title
1.	Algeria	Establishment of a programme for the developlment of the pharmaceutical industry.
2.	Burma	Preparatory phase for the establishment of pharmaceutical fermentation pilot plant.
3.	India	Mordernization of facilities for immunobiological and chemotherapeutic research at Bengal Immunity Research Institute.
4.	Iran	Transfer of technology for the production of bulk synthetic drugs in a multi purpose pilot plant.
5.	India	Assistance in human vaccine production.
6.	Mexico	Assistance in human vaccine production.
7.	Mongolia	Transfer of technology for production of bioactive substances from animal by-products.
8.	Nicaragua	Local production of essential drugs.
9.	Panama	Establishment of a regional centre for pharmaceutical technology.
10.	Regional Latin America	Establishment of a development plan for an integrated regional production of biologicals.
11.	Tanzania	Assistance to the livestock vaccine production.
12.	Venezuela	Transfer of technology for the production of bulk synthetic drugs in a multi-purpose pilot plant.
13.	Vietnam	Transfer of technology for production of bioactive substance from animal by-products.
14.	Zimbabwe	Preparatory assistance towards the establishment of an Institute for Research and Development for traditional medicines.