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United Nations Industrial Development Organization

Second Consultation on the Pharmaceutical Industry, Budapest, 21-25 November 1983

PROCESS REPORT OF ACTIVITIES TAKEN ON CONSULTATIONS ON THE PHARMACEUTICAL INDUSTRY

prepared by
the UNIDO Secretariat

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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 Consultations. 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 Consultation on the Pharmaceutical Industry was convened at Lisbon, Portugal, from 1 to 5 December 1980.

The Second Consultation on the Pharmaceutical Industry is being convened at Budapest, People's Republic of Hungary, from 21 to 25 November 1983.


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INTRODUCTION

1. This progress report present 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, and includes a comprehensive expose of priority problems of developing countries in pharmaceuticals as appraised at the interregional meeting at Cairo, Egypt (see para. 7).

Chapter II shows the conclusions and recommendations of the First Consultation including topics discussed but not given recommendations for action by UNIDO.

Chapter III presents 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 recommended issue.

Chapter IV gives the background to identifying new issues for the Second Consultation.

Chapter V shows the four issues being presented for discussion at the Second Consultation, including a brief description and its locus for discussion.

The Annexures provide relevant information on the UNIDO list of 26 essential drugs, provisional agenda, list of documents and technical assistance projects in pharmaceuticals.

2. To facilitate the participants' preparations for the Second 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 commentary and/or recommendations for action by UNIDO.

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 the main studies, field surveys, industrial profiles and other documents and proposals in their original form.

Each paper is self-contained as far as practicable, in order to give the reader the necessary judging elements on its contents without having to resort to other papers for information.
I. THE SELECTION OF ISSUES FOR THE FIRST CONSULTATION

3. In order to identify the issues suitable for Consultations on the Pharmaceutical Industry, UNIDO convened two panel meetings in July 1977 and March 1978 with participants from developed and developing countries. Thereafter an interregional expert group meeting of developing countries was convened in January 1979 with observers from the industry. Their recommendations on issues for discussion were reviewed by the Global Preparatory Meeting for Consultations on the Pharmaceutical Industry in April 1980, which recommended the final issues that were presented to the First Consultation.

A. PANEL MEETINGS OF EXPERTS ON THE PHARMACEUTICAL INDUSTRY

4. The first panel meeting of experts was convened in Vienna, Austria in July 1977 as a first step in making preparations for a consultation meeting on the pharmaceutical industry. It was attended by 19 participants from 15 countries (report UNIDO/EX.24). UNIDO presented a list of 16 topics which might be chosen as issues for the First Consultation. The panel discussed all the topics but it did not make a selection of issues. It concluded that a second meeting of the panel might need to be convened.

5. The second panel meeting of experts was convened in Vienna, Austria in March 1978. It was attended by 18 participants from 17 countries and observers from international organizations (report ID/WG.267/4/Rev.1). The second panel discussed the 8 topics presented by UNIDO but it did not make a selection of issues. However, its conclusions and recommendations included detailed criteria and guidelines that helped the interregional meeting in Egypt to recommend priority issues for the First Consultation. Among the main recommendations of the panel were the following:

a) the preparation of national lists of drugs to meet local health needs, using WHO's list of essential drugs as reference. An initial list of 12 drugs was agreed, additions to which should include immunologicals and sulfa drugs.
b) an agreed set of criteria for selecting drugs for production in developing countries emphasizing drug efficacy and safety against locally prevalent diseases, its economic feasibility for local manufacture up to plant capacity sufficient to meet regional and interregional demand, technology selection appropriate to local conditions, and availability of production know-how whether patented or not.

c) an agreed set of terms and conditions for transfer of technology and know-how.

d) co-operation with the international pharmaceutical industry, among developing countries and support from UN Organizations to develop local production of drugs and formulations.

B. INTERREGIONAL EXPERT GROUP MEETING

6. The interregional meeting to prepare for consultations on the pharmaceutical industry was convened at Cairo, Egypt in January 1979 to identify priority issues that developing countries were to discuss with developed countries at Consultation meetings on the industry. Participants from 12 developing countries and 9 regional organizations were present. (report ID/WG. 292/3 Rev.1).

7. The interregional meeting arrived at the following conclusions:

a) The pharmaceutical industry should make an increased contribution to health care in developing countries. However, most developing countries have no pharmaceutical manufacturing facilities, some have plants to formulate a limited range of drugs, only a few have some plants for the manufacture of drugs.

b) As a result, the availability of pharmaceutical products, bulk drugs for formulations and intermediate products for drug manufacture are met by imports. The rising prices of these imports compounded by foreign exchange restrictions make it necessary to consider local formulation and drug manufacture as the main priority least health care for the majority of the population is going to suffer.
c) Developing countries have tended to imitate the pattern of pharmaceutical supply in developed countries, where many different products are sold in a large number of formulations and dosage forms. Since developing countries face important limitations on pharmaceutical production know-how and financial resources, a different pattern of pharmaceutical supply should be followed by emphasizing fewer formulations and the local production of drugs required to meet their national health needs.

d) To attain the above, their national drug policies should aim to make available the drugs required by each country and to avoid the excessive proliferation of different formulations, brands and dosage forms. It should also guide their national pharmaceutical industry towards meeting the above aims.

e) The main constraints for establishing and/or developing the pharmaceutical industry in developing countries were identified as inadequate technological capability, lack of trained personnel, high cost and scarcity of imported bulk drugs and its intermediates, financing restrictions and lack of well-defined national drug policies.

f) The above constraints partly stem from the structure of their pharmaceutical industry which evolved mainly with the cooperation of large pharmaceutical corporations that brought along with process technology and know-how, the patterns of business customary to developed countries. This development led to the local offering of a broad range of branded products not always adapted to national health needs, a fragmented vertical integration to produce bulk drugs and a limited technological capability to absorb and generate pharmaceutical technology and know-how.
g) To redress the above unbalance, developing countries are striving to modify the current framework for international cooperation on pharmaceuticals, to enable them the setting up of an integrated industry that gives priority to producing a range of essential drugs and its subsequent formulations into dosage forms appropriate to their health care needs.

8. The interregional meeting recognized the need to develop the local pharmaceutical industry and recommended that the priority issues for discussion at the First Consultation on the Pharmaceutical Industry, should be the following:

i) the availability of, and a pricing scheme for, intermediates and bulk drugs.

ii) a model form of licensing agreement for the transfer of technology to produce essential bulk drugs and formulations.

iii) international cooperation and in particular greater cooperation among developing countries in pharmaceuticals.

Further issues were recommended concerning the financing of pharmaceutical projects in developing countries, and the production of pharmaceuticals derived from medicinal plants.

C. GLOBAL PREPARATORY MEETING

9. The Global Preparatory Meeting for Consultations on the Pharmaceutical Industry was convened at Cancun, Mexico in April 1980 to advise UNIDO on the issues that should be discussed at the First Consultation Meeting on the Pharmaceutical Industry. It was attended by 45 participants from 29 countries and 14 representatives from 6 international organizations (report ID/WG.317/3).

10. At the Global Preparatory Meeting, UNIDO presented three issues that might be considered by the First Consultation. These issues were
arrived at after considering the recommendations of the expert group meetings mentioned in paragraph 3, and the conclusions of detailed case studies on the constraints faced by selected developing countries in establishing and expanding their pharmaceutical industry. These issues were considered suitable because they could be solved by greater international cooperation. They are the following:

a) the pricing and availability of intermediates and bulk drugs.
b) guidelines for licensing arrangements for the transfer of technology for the manufacture of essential drugs and formulations.
c) the availability, terms and conditions for the transfer of technology for the manufacture of 26 essential drugs. This issue defines the more pressing problem towards achieving both international cooperation and greater cooperation among developing countries in pharmaceuticals.

11. After considerable discussions, the Global Preparatory Meeting recommended that the First Consultation should consider the following three issues:

a) issue 1: The pricing and availability of intermediates and bulk drugs.
b) issue 2: Contractual arrangements for the production of drugs, covering two parts:
   i) relevant issues to be taken into account when negotiating a transfer of technology agreement.
   ii) preparation of guidelines for licensing arrangements for the transfer of technology to manufacture essential drugs and formulations.
c) issue 3: The availability, terms and conditions for the transfer of technology for the manufacture of essential drugs included in the illustrative list prepared by UNIDO in consultation with WHO.
In addition, some participants felt that vaccines and sera should be included in the above list of issues but the Meeting considered that focusing the discussions on the three selected issues would be more practical to achieve results.

II. CONCLUSIONS AND RECOMMENDATIONS OF THE FIRST CONSULTATION

12. 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 adopted the following conclusions and recommendations (report of the First Consultation: ID/259, paras 1 to 7):

13. Issue 1: To set up a UNIDO Committee of Experts on pharmaceuticals composed of experts from developed and developing countries to discuss the technical and economic aspects of the availability of intermediates and bulk drugs.

a) The Committee will be dedicated to the concept of, and committed to highlighting the need for, evolving a better understanding of matters relating to the availability of the 26 essential drugs included in the UNIDO illustrative list, and to assisting developing countries in the production of these bulk drugs and its intermediates.

b) The members of the Committee, which would be a reasonably small number, would be experienced experts selected by UNIDO giving preference to experts having participated in the First Consultation and representing all geographical groups, including countries with a major pharmaceutical industry.

c) The Committee will complete its work in due time for the Second Consultation.

d) There also was a consensus on entrusting UNIDO with the preparation of a directory of sources of supply of essential drugs from developing and developed countries (para. 35).
14. **Issue 2:** In view of the discussions held on this issue, and the substantial differences expressed as to the content of items which could be incorporated into various contractual arrangements between parties interested in transfer of technology in the pharmaceutical industry, the First Consultation recommends that:

a) UNIDO, in co-operation with an ad-hoc panel of experts, selected on the basis of equitable geographical distribution, should prepare a document, complete with the necessary background notes, on various terms, conditions and variations thereof that could be included in contractual agreements.

b) In addition, UNIDO should undertake a detailed study on relevant issues to be taken into account when negotiating transfer of technology agreements as put forward in the issue paper to this issue 2 (ID/WG.331/2 and Add.1), taking into account the experience of developed countries.

15. **Issue 3:** After considering this issue, the First Consultation arrived at the following conclusions:

i) The 26 essential drugs identified by UNIDO and essential and well defined products based on medicinal plants constitute an illustrative list for undertaking basic manufacture in developing countries;

ii) The developing countries as a group constitute large markets for these drugs where in certain cases the patents have lapsed;

iii) There is a willingness expressed by developed countries of market economies, developed countries of centrally planned economies and pharmaceutical corporations to enable the transfer of technology to developing countries, bearing in mind the human health needs aspect of such transfers of technology.

iv) Transfers of technology have to take place on mutually acceptable and equitable terms;

v) Manufacture to be based on maximum feasible upstream integration to raw materials.
16. On this issue 3, the First Consultation recommended that:

a) such mutually acceptable transfers of technology should be facilitated through UNIDO by providing reference information relevant to the transfer of technology, including technical aspects such as the level of production, magnitude of investment, inputs, infrastructure, etc., which could be a significant aid to individual developing countries in bilateral negotiations for transfer of technology. The results of such transfers and experience should be brought to the attention of the Second Consultation.

b) The transfer of technology for drugs referred to in para. 15(i) above should be acceptable to recipients and suppliers of technology. Serious consideration should be given to joint ventures, licenses and other commercial arrangements, with a view to UNIDO assisting developing countries in improving their negotiating positions through its reference and information resources, in order to overcome impediments and to facilitate imports and exports with a view to increasing trade in raw materials, intermediates, bulk drugs, equipment and finished goods, and to increasing the transfer of technology to developing countries.

c) It was agreed that technical co-operation among developing countries could play an effective role in the development of the pharmaceutical industry in developing countries, especially in respect of the following: the need to develop local research and development to absorb, assimilate and further develop the technology acquired; training; quality control; exchange of information and experience; and trade in raw materials and finished products.
17. Other topics which were discussed but not given specific recommendations for action were:

a) Technology for medicinal plants. Discussions were held highlighting its importance to developing countries. A consensus general conclusion was obtained but no recommendation was made on this topic.

b) Cooperation among developing countries. Discussions indicated its importance to developing countries and stressed the technical over the economic aspects. Emphasis was given to technology and research and development. A consensus general agreement was achieved but without specific requests for action by UNIDO.

18. In addition, lengthy discussions took place on the Global Study on the pharmaceutical industry presented by UNIDO and supplemented at the meeting by conference room papers given by a country and groups of countries. No consensus conclusions were obtained.

III. ACTION TAKEN TO IMPLEMENT THE RECOMMENDATIONS OF THE FIRST CONSULTATION

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

a) to convene a round table meeting on the development of the pharmaceutical industry to advise UNIDO on actions to be taken to implement the recommendations of the First Consultation, including the compositions of the Committee of Experts (issue 1) and the Ad-hoc Panel of Experts (issue 2).

b) to carry out a survey on drugs for which technology could be offered (issue 3), considering the willingness expressed by developed countries and the international pharmaceutical industry to enable the transfer of technology to developing
countries (report of the First Consultation: ID/259, paras. 4(c) and 76). Regretably, the results of the survey were unsatisfactory due to a poor response on the questionnaire.

20. The Round Table Meeting on the Development of the Pharmaceutical Industry was convened at Mohammedia, Morocco from 2 to 3 December 1981. It was attended by 22 participants from 15 countries and the industry (report UNIDC/PC.33).

The meeting arrived at the following conclusions and recommendations:

a) **Issue 1: availability and pricing of essential bulk drugs and intermediates.**

   i) It recognized the existence of a problem concerning prices of bulk drugs and intermediates and recommended that the committee of experts to be established should pay particular attention to those bulk drugs and intermediates for which there are only limited sources of supply. Nine drugs out of the UNIDO list of 26 essential drugs were identified as having limited sources of supply. Annexure A presents such a list.

   ii) The Committee of Experts should include representatives from those manufacturers of intermediates and bulk drugs for which there are limited sources of supply.

   iii) UNIDO should prepare a directory of sources of supply of the 26 essential drugs and their intermediates, including details and specifications. The directory should be updated periodically.
b) issue 2: contractual arrangements.

i) it recommended guidelines and main principles to be considered in the preparation of documents on contractual arrangements as well as other items which should be included in such arrangements.

ii) it advised on the composition of the ad-hoc panel which should be kept small and not more than 12 in number.

iii) it defined the scope of the study on "relevant topics to be taken into account when negotiating transfer of technology agreements".

21. Following the advice of the Round Table Meeting, the Committee of Experts was convened in Paris, France in October 1982, and the Ad-hoc Panel of Experts was convened twice in Vienna, Austria in December 1982 and April 1983 respectively. Further, a meeting on cooperation among developing countries is being convened in Tunis, Tunisia in September 1983 to define the scope of their cooperation.

A. ISSUE 1: AVAILABILITY AND PRICING OF BULK DRUGS AND INTERMEDIATES

22. Upon the advice of the Round Table Meeting, the Committee of Experts on Pharmaceuticals was convened in Paris, France from 1 October 1982. It was attended by 16 participants from 13 countries (report UNIDO/PC.59).

In presenting this issue, the following features were highlighted:

a) the existing disparity between prices of bulk drugs and their intermediates.

b) prices of intermediates were a constraint to producing bulk drugs and formulations into dosage forms in developing countries.
c) non-availability of technology for the production of the 26 essential bulk drugs and their intermediates (see para. 19(b)).

In addition, a draft directory of sources of supply of bulk drugs, their intermediates and some raw materials was presented. An addendum to it gave a mathematical concept for evaluating the cost of intermediates in relation to the cost of producing its bulk drugs.

23. The Committee of Experts reached the following conclusions and recommendations:

a) In order to arrive at prices for intermediates which are in reasonable relationship with the cost of bulk drugs, negotiations on supply and prices for those products should be conducted between suppliers and purchasers based on mutual acceptance.

b) the quantitative requirements of interested developing countries should be assessed and indicated to the manufacturers in order to negotiate their long-term supply to developing countries at reasonable and mutually acceptable prices.

c) it recommended UNIDO to undertake a study on transfer of technology for the manufacture of intermediates and bulk drugs based on non-confidential information, in collaboration with producers from developed and developing countries. Such study could significantly aid individual developing countries in bilateral negotiations for transfer of technology.

d) particular attention should be given the least developed countries for whom the problem of availability and quality control of bulk drugs and formulations including vaccines at mutually acceptable conditions and prices, is of crucial importance.
24. The above recommendations pointed out to a two-prong alternative solution on the supply of bulk drugs and intermediates to developing countries, and to assisting developing countries in the manufacture of formulations of bulk drugs into dosage forms.

a) production of bulk drugs and intermediates in developed countries to meet the collective requirements of interested developing countries (para. 23(b)).

b) production of bulk drugs and intermediates in developing countries through transfer of technology. The study requested on this topic (para. 23(c)) effectively includes this issue into issue 3 "transfer of technology", and the actions taken to implement it are given in para. 32.

c) to assist in the manufacture of formulations of bulk drugs, UNIDO compiled a directory of sources of supply of bulk drugs and is preparing industrial profiles for this purpose.

25. UNIDO sent out a questionnaire to ascertain the drug and intermediate needs of a number of developing countries. Some of the countries that replied expressed certain reservations about the lack of information on sources of supply, criteria for purchases, etc. Information on intermediates was limited since in few cases bulk drug plants were idle due to high prices of imported intermediates and out-of-date technology, which rendered those plants uneconomic to operate.

The points raised by developing countries in the above context would need particular consideration in attempting to work out a solution on this issue.

26. Additional substantive information on this issue is given in the background paper prepared for the combined issues 1 and 3 (ID/WG.393/9).

B. ISSUE 2: CONTRACTUAL ARRANGEMENTS FOR THE PRODUCTION OF DRUGS

27. Upon the advice of the Round Table Meeting, the Ad-hoc Panel of Experts on Contractual Arrangements in the Pharmaceutical Industry was convened twice in Vienna, Austria from 15 to 17 December 1982 and 25 to 29 April 1983 respectively.
In presenting the issue, the constitution of the Ad-hoc Panel was clarified and the features of the three documents for discussion were highlighted.

28. The first meeting of the Ad-hoc Panel completed the revision of document "transfer of technology for the manufacture of the bulk drugs/intermediates included in UNIDO's list" (ID/WG.393/1).

The second meeting of the Panel completed the review of the remaining two documents "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 the three revised documents be presented to the Second Consultation.

29. In addition, the second meeting of the Ad-hoc Panel recommended that UNIDO present to the Second Consultation the following:

a) studies on the following topics if time and resources permit:
   i) guidelines on patent law and its consequences for producers and licensing agreements relating thereto,
   ii) a survey on industrial protection in developing countries on pharmaceutical product and process and export restrictions,
   iii) a survey of WHO's essential list of drugs to examine whether patent protection exists.

b) to prepare the following additional documents on contractual arrangements:
   i) items which could be included in turnkey contractual arrangements for the setting up of a plant for the production of bulk drugs/intermediates included in UNIDO's list.
ii) arrangements for technical assistance for the formulation of pharmaceutical forms.

30. UNIDO complied with the recommendations of the Ad-hoc Panel and in presenting to the Second Consultation the three documents mentioned in para. 28, the recommendations given in para. 29(b), and the study mentioned in para. 29(a)(ii).

Additional substantive information is given in the background paper to this issue (ID/WG.393/7).

C. ISSUE 3: TRANSFER OF TECHNOLOGY FOR THE MANUFACTURE OF THE ESSENTIAL DRUGS INCLUDED IN UNIDO'S ILLUSTRATIVE LIST

31. Although the First Consultation only gave general recommendations on this issue, the discussions and recommendations of the Committee of Experts which discussed issue 1, 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 (see paras. 23 and 24(b)).

32. In order to prepare the study recommended by the Committee in para. 23(c) above, a questionnaire was sent to 130 major pharmaceutical producers and organizations in developed and developing countries. Only 14 replies were received covering 16 drugs and 12 intermediates, 20 technology holders expressed regret. Further, some companies requested that the information they supplied be treated as confidential and thus it should not be published.

33. Despite the above disappointing outcome and considering the intention of the Committee to solve this issue through production in developing countries, UNIDO continued its search and eventually became successful in identifying some independent research-based technology holders willing to transfer technology for the production of 21 out of the 26 essential drugs included in UNIDO's list.
34. Additional substantive information on this issue 3 is given in the background paper prepared for the combined issues 1 and 3 (ID/WG.393/9).

IV. THE IDENTIFICATION OF NEW ISSUES

35. Throughout the preparations for the First Consultation, three possible new issues kept on repeating in all the expert group meetings mentioned in para. 3. They are medicinal plants, immunologicals (vaccines and sera), and cooperation among developing countries.

36. Concerning the first two issues, their background for selecting them as issues for discussion at the Second Consultation is given herebelow. The third possible issue has been partially included in issue 3, transfer of technology, and it is expected to be complemented by the recommendations of the meeting on co-operation among developing countries convened for early September 1983 in Tunis, Tunisia.

A. MEDICINAL PLANTS

37. In the last century, medicinal plants have developed new applications as raw materials for bulk drugs and intermediates, besides to its customary use in traditional medicine. The empiric clinical benefits of this natural pharmacopeia led to characterize new plant-based drugs by isolating their active principles.

38. The high cost of chemical drugs encouraged a number of developing countries to complement modern medicine with traditional medicine to spread health care coverage to the majority of the population at reasonable cost. In general, it is cheaper for developing countries to use plant extracts instead of pure active principles for the cost of isolating those principles is high.
39. However, prescriptions in developed countries contain over 180 active plant principles, about 45% of them are used as pure principles, the rest is used as crude drugs or crude extracts. Customarily, developing countries export only crude extracts from medicinal plants which are thereafter processed in developed countries to obtain pure (or crude) drugs with a value added about 10 times higher than the price of crude extracts.

40. Financial and infrastructural limitations did not enable developing countries to carry out chemical testing and develop adequate process technologies to extract active plant principles used in bulk drugs and intermediates. This technology is generally available in developed countries whilst most plant raw material is obtained in developing countries.

41. Hence the production of active plant principles in developing countries require transfer of relevant technology according to the degree of uniqueness of each plant specie, the assurance of continuous supply of medicinal plants, and the identification of the local flora and fauna characterized to contain known active principles.

B. BIOLOGICALS (VACCINES)

42. The disease pattern of developing countries is quite different from that of developed countries for communicable diseases are still the leading cause of death in those countries.

In particular, in the least developed countries infectious diseases are both the leading cause of death and of disabling over 5 million children annually.

43. To expand health coverage to the majority of the population, drug-based curative medicine is necessary but it is insufficient and expensive. Conversely, preventive medicine is a more economical approach to control infectious diseases than cure and it is the only way to prevent disability.
44. Within preventive medicines, vaccines represent the active immunization products. There are two main groups of vaccines, the classical and the modern or improved. The technology of the former were empirically developed in the past 60 years, whilst that of the latter is the outcome of systematic research and development.

45. Technology to produce classical vaccines is generally available but to assimilate this technology a long manufacturing experience is needed to master the difficulties arising out of often ill-defined empirical manufacturing process. Technology to manufacture modern vaccines is difficult to obtain for generally it is patented, there is one or few licensors, and it is expensive.

46. Since developed countries have been successful in their immunization programmes so that communicable diseases only affect a small percentage of their population, their industry has been showing decreasing interest in producing vaccines hence rendering most developing countries defenceless against the locally prevailing major communicable diseases for lack of adequate imports.

47. Developing countries, which possess certain manufacturing capability in some classical vaccines and face difficulty in securing foreign currency to defray imports (in some modern vaccines there is a supply shortage even to cover the needs of developed countries), have the need to produce both classical and modern vaccines to safeguard the health of their populations.

V. ISSUES PRESENTED TO THE SECOND CONSULTATION

48. The issues which are being presented for discussion at the Second Consultation on the Pharmaceutical Industry are the following:

a) **issue 1**: Contractual arrangements for the production of drugs.

b) **issue 2**: Availability, pricing and transfer of technology for bulk drugs and their intermediates
c) **Issue 3**: The development of drugs based on medicinal plants.

d) **Issue 4**: The manufacture of vaccines in developing countries.

The full presentation of the above issues is given in the corresponding issue and background papers listed in Annexure C.

49. To facilitate the participants' preparations for discussions at the Second Consultation the following annexures are included.

i) **Annexure A** - UNIDO's List of 26 Essential Drugs including the 9 priority drugs for which sources of supply are limited.

ii) **Annexure B** - The provisional agenda of the Consultation. Efforts have been made to maintain the headings of issues stemming from the First Consultation and the generic names of the new issues.

iii) **Annexure C** - List of Documents

iv) **Annexure D** - UNIDO Technical assistance projects in pharmaceuticals.
ANNEXURE A

Illustrative UNIDO List of 26 Essential Drugs

A. ANALGESICS
   1. Acetylsalicylic acid *
   2. Paracetamol

B. ANTI-INFECTIVE DRUGS
   Anthelmintic drugs
   3. Mebendazole
   4. Piperazine

   Antibacterial drugs
   5. Ampicillin *
   6. Benzylpenicillin
   7. Erythromycin
   8. Sulfadimidine *
   9. Tetracycline *

   Antifilarial drugs
   10. Diethylcarbamazine *

C. BLOOD PRODUCTS
   17. Plasma fractions

D. CARDIOVASCULAR DRUGS
   Antihypertensive drugs
   18. Hydralazine
   19. Propranolol
   20. Reserpine

E. DIURETICS
   21. Furosemide

F. DRUGS AFFECTING THE BLOOD
   22. Hydroxocobalamine

G. HORMONES
   Antidiabetic agents
   23. Insulin
   Oral contraceptives
   24. Ethinylestradiol/Levonorgestrel

H. VITAMINS
   25. Ascorbic acid
   Retinol

Antituberculosis drugs

14. Ethambutol *
15. Isoniazid *
16. Streptomycin

Note: This list was prepared by UNIDO in consultation with WHO. The classification and nomenclature was updated according to WHO's "The Use of Essential Drugs", Technical Report Series No. 685, 1983.

* Selected 9 priority drugs for which sources of supply are limited (report: UNIDO/PC.33)
ANNEXURE B

Provisional Agenda

1. Opening of the Consultation
2. Election of the Officers
3. Adoption of the Agenda
4. Progress Report on actions taken to implement the recommendations of the First Consultation on the Pharmaceutical Industry
5. Contractual arrangements for the production of essential drugs
6. Price and availability of bulk drugs, intermediates and transfer of technology for the manufacture of the drugs included in the UNIDO List of 26 Essential Drugs
7. Proposals for new issues
   (a) - Medicinal plants
   (b) - Biologicals
8. Conclusions and recommendations
9. Adoption of the Report of the Meeting
ANNEXURE C

List of documents for the Second Consultation on the Pharmaceutical Industry

1. Progress Report ID/WG.393/5

Issue and background papers

2. Contractual Arrangements for the Production of Drugs - Issue Paper ID/WG.393/6
   - Items which could be incorporated in contractual arrangements for the transfer of technology for the manufacture of those bulk drugs/intermediates included in UNIDO's Illustrative List ID/WG.393/1
   - Items which could be included in contractual arrangements for the setting up of a plant for the production of bulk drugs (or intermediates) included in UNIDO Illustrative List ID/WG.393/4
   - Items which could be included in licensing arrangements for the transfer of technology for the formulation of pharmaceutical dosage forms ID/WG.393/3

3. Contractual Arrangements for the Production of Drugs - Background Paper ID/WG.393/7

4. Availability, pricing and transfer of technology for bulk drugs and their intermediates - Issue Paper ID/WG.393/8

5. Availability, pricing and transfer of technology for bulk drugs and their intermediates - Background Paper ID/WG.393/9

6. The development of drugs based on medicinal plants - Issue Paper ID/WG.393/10

7. The development of drugs based on medicinal plants - Background Paper ID/WG.393/11

8. The manufacture of vaccines in developing countries - Issue Paper ID/WG.393/12

9. The manufacture of vaccines in developing countries - Background Paper ID/WG.393/13

Reference Papers

10. Relevant topics to be taken into account in the preparatory phase of technology transfer arrangements for the production of pharmaceuticals ID/WG.393/14
<table>
<thead>
<tr>
<th></th>
<th>Title</th>
<th>Document ID</th>
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</thead>
<tbody>
<tr>
<td>11.</td>
<td>Summary of industrial property protection on pharmaceuticals in to developing countries</td>
<td>ID/WG.393/15</td>
</tr>
<tr>
<td>12.</td>
<td>Multipurpose plant for the production of UNIDO's List of Essential Drugs based on raw materials and intermediates</td>
<td>ID/WG.393/16</td>
</tr>
<tr>
<td>13.</td>
<td>Directory of Sources of Supply of 26 Essential Drugs, their chemical intermediates and some raw materials</td>
<td>ID/WG.393/2</td>
</tr>
<tr>
<td>14.</td>
<td>Water use and effluent in the Pharmaceutical Industry</td>
<td>UNIDO/IS.388</td>
</tr>
<tr>
<td>15.</td>
<td>Prospects for production of vaccines and other immunizing agents in developing countries</td>
<td>UNIDO/IS.389</td>
</tr>
<tr>
<td>16.</td>
<td>The need of drug policies</td>
<td>ID/WG.393/17</td>
</tr>
<tr>
<td>17.</td>
<td>Industrial profiles of pharmaceutical production units for formulations and bulk drugs</td>
<td>ID/WG.393/18</td>
</tr>
</tbody>
</table>
# Annexure D

## List of Projects

1. **Under Implementation 1982/1983**

   **a) Asia**

<table>
<thead>
<tr>
<th>Country</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>Modernisation of Facilities for the Manufacture of Anti-Malarial Drugs</td>
</tr>
<tr>
<td>India</td>
<td>Assistance in the Manufacture of Dapsone</td>
</tr>
<tr>
<td>Mongolia</td>
<td>Establishment of a Pilot Plant for Processing of Biochemical Products – Preparatory Assistance</td>
</tr>
<tr>
<td>Nepal</td>
<td>Primary Health Support Services Programme</td>
</tr>
<tr>
<td>Nepal</td>
<td>Strengthening the Royal Drugs Research Laboratory</td>
</tr>
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</table>

   **b) Africa**

<table>
<thead>
<tr>
<th>Country</th>
<th>Title</th>
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</thead>
<tbody>
<tr>
<td>Cameroon</td>
<td>Assistance au Development de la Production de Vaccins, d'Huiles Essentielles et de Produits Pharmaceutiques</td>
</tr>
<tr>
<td>Guinea</td>
<td>Rehabilitation et Creation des Unites de Fabrication Locale Des Medicaments</td>
</tr>
<tr>
<td>Rwanda</td>
<td>Production de Medicaments a Base de Plantes Medicinales</td>
</tr>
<tr>
<td>Tanzania</td>
<td>Assistance for the Production of Plant Derived Pharmaceuticals</td>
</tr>
<tr>
<td>Upper Volta</td>
<td>Assistance à la production de Produits Pharmaceutiques à partir de Plantes Medicinales</td>
</tr>
<tr>
<td>Zanzibar</td>
<td>Assistance in the Establishment of a Pharmaceutical Plant in Zanzibar</td>
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</tbody>
</table>
2 - PROJECTS FINALISED DURING THIS PERIOD

a) Africa
   Cape Verde
   Mozambique
   Zambia

b) Latin America
   Cuba

<table>
<thead>
<tr>
<th>Country</th>
<th>Project Description</th>
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<tbody>
<tr>
<td>Cuba</td>
<td>Establishment of a Multipurpose Pilot Plant in Cuba for the Production of Synthetic Drugs</td>
</tr>
<tr>
<td>Cuba</td>
<td>Centre for the Development of the Pharmaceutical Industry</td>
</tr>
<tr>
<td>Nicaragua</td>
<td>Assistance to the Ministry of Industry for the Pharmaceutical Sector</td>
</tr>
<tr>
<td>Cape Verde</td>
<td>Pilot Plant for the Production of Medicaments in the Cape Verde Islands</td>
</tr>
<tr>
<td>Mozambique</td>
<td>Production of Oral Rehydration Salts</td>
</tr>
<tr>
<td>Zambia</td>
<td>Intravenous Fluids Plants</td>
</tr>
<tr>
<td>Cuba</td>
<td>Establishment of a Regional Fermentation Programme for the Production of Antibiotics and other Pharmaceuticals in Latin America</td>
</tr>
</tbody>
</table>
3 - **TO BE IMPLEMENTED IN 1984**

<table>
<thead>
<tr>
<th><strong>Country</strong></th>
<th><strong>Title</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Asia</strong></td>
<td></td>
</tr>
<tr>
<td>India</td>
<td>Techno-economic Feasibility Study for the Utilization of Medicinal and Aromatic Plants</td>
</tr>
<tr>
<td>Nepal</td>
<td>Processing of Medicinal Plants Cultivated and Collected in Nepal</td>
</tr>
<tr>
<td>Mongolia</td>
<td>Establishment of a Pilot Plant for Processing of Meat</td>
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<tr>
<td>Mongolia</td>
<td>Pilot Plant for Baby Food Production</td>
</tr>
<tr>
<td>Vietnam</td>
<td>Pilot Production of Medicines Using Indigenous Raw Materials</td>
</tr>
<tr>
<td><strong>Africa</strong></td>
<td></td>
</tr>
<tr>
<td>Mozambique</td>
<td>Creation of a Base for a Pharmaceutical Industry</td>
</tr>
<tr>
<td><strong>Latin America</strong></td>
<td></td>
</tr>
<tr>
<td>Brasil</td>
<td>Establishment of a Multipurpose Plant for the Production of Synthetic Drugs</td>
</tr>
<tr>
<td>Mexico</td>
<td>Establishment of a Regional Research Centre for Biotechnology and Genetic Engineering</td>
</tr>
<tr>
<td>Peru</td>
<td>Establishment of a Centre for Biotechnology applied to Pharmaceuticals</td>
</tr>
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