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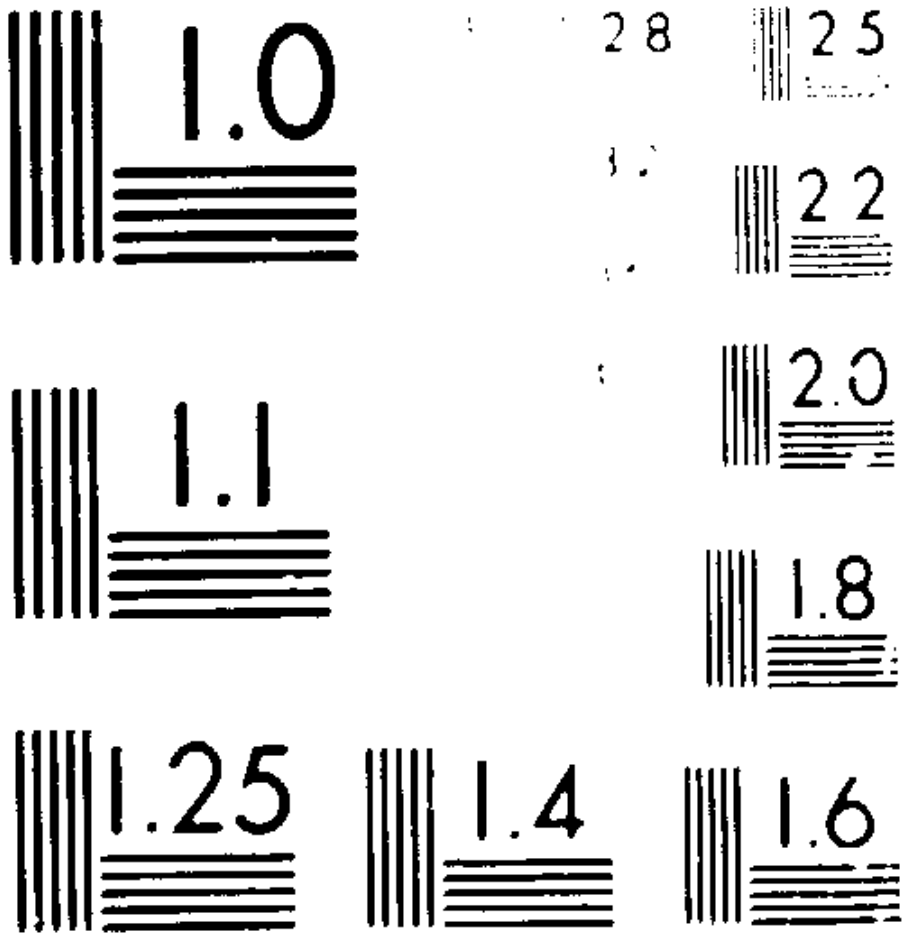
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Global Preparatory Meeting for
Consultations on the Pharmaceutical
Industry

Cancun, Mexico, 24-27 April 1980

DRAFT REPORT*

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ANNEXURES

INTRODUCTION

1. 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 developing and developed countries with the objective of raising the developing countries' share in world industrial output through increased international co-operation. That recommendation was endorsed by the General Assembly at its seventh special session in September 1975.

2. The System is being implemented under the guidance of the Industrial Development Board, the policy-making organ of UNIDO; it decided in 1976 that Consultations should be held among member countries and that participants may include officials of Governments as well as representatives of industry, labour, consumer groups, etc., as deemed appropriate by each Government. Relevant organizations are also invited to participate. Attendance has been 150-250 participants from 50-70 countries and the conclusions and recommendations of each Consultation have been adopted by consensus.

3. To prepare for Consultations on the Pharmaceutical Industry, two panels of experts from developing and developed countries were convened in June 1977 and February 1978. An Interregional Meeting to prepare for Consultations on the Pharmaceutical Industry was held in January 1979 at Cairo, Egypt. Through these meetings, the UNIDO secretariat identified the issues that might be suitable for Consultations on this industry.

4. When considering the programme of Consultations for 1980-81, the Board authorized the UNIDO secretariat to convene the First Consultation on the Pharmaceutical Industry in 1980.

5. The purpose of the Global Preparatory Meeting was to advise on the issues that should be discussed at the First Consultation on the Pharmaceutical Industry to be convened in Lisbon, Portugal from 1-5 December 1980.

6. Bearing in mind the ongoing programme of co-operation between UNIDO, WHO and UNCTAD on this industry, representatives of WHO and UNCTAD were invited to participate in the Meeting. Attention was drawn to WHO's Action Programme on Essential Drugs approved by the World Health Assembly in 1978. In this connection, it was noted that the Executive Heads of WHO and UNIDO entered into an agreement in August 1979 to co-ordinate the efforts of the two Organizations on the development of the pharmaceutical industry:

> "WHO's contribution would focus on the identification of health needs and on the definition and implementation of health and drug policies; UNIDO, on its part, would focus on the definition and implementation of industrial production policies, including pharmaceutical production and utilization of natural resources".

I. CONCLUSIONS AND RECOMMENDATIONS

7. The Global Preparatory Meeting recommended that the First Consultation Meeting on the Pharmaceutical Industry should consider the following three issues:

- The pricing and availability of intermediates and bulk drugs;
- Contractual arrangements for the production of drugs
  Part 1: Relevant issues to be taken into account when negotiating a transfer of technology agreement;
  Part 2: Preparation of guidelines;

  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.

II. ORGANIZATION OF THE MEETING

8. The Global Preparatory Meeting was convened in Cancun, Mexico from 24-27 April 1980 at the invitation of the Government of Mexico.

9. There were 97 persons attending the Meeting, including 43 participants from 29 countries, 14 representatives from 6 organizations, and 40 observers from Mexico.

10. The Meeting was formally opened by Dr. Carlos Gual Castro, Vice-Minister of Assistance, Ministry of Health and Assistance, in the presence of Mr. Jesus Martinez Ross, Governor of the State of Quintana Roo. The Vice-Minister stressed the urgency of expanding the pharmaceutical and pharmaceutical chemical industry's contribution to national health services in developing countries.

11. The Meeting elected Mr. Natan Warman, Vice-Minister of Industrial Development, Secretaria de Patrimonio y Fomento Industrial, Mexico as Chairman and Dr. Vischer, Member of the Board of Directors of Ciba-Geigy and representative of Switzerland as Vice-Chairman.

12. Mr. A.Hacini, Head of the Negotiations Section, responsible for organizing consultations, explained the origin and scope of the UNIDO System of Consultations and stressed the unique features of UNIDO's consultations, namely (a) the continuing nature of the System, (b) the emphasis on reaching consensus;and (c) the direct contribution made by representatives of industry.

13. Ms. A. Tcheknavorian-Asenbauer, Chairperson of the UNIDO Internal Task Force to prepare for Consultations on the Pharmaceutical Industry, introduced the three issues which the UNIDO secretariat had suggested might be suitable for consideration by the First Consultation. These issues had been selected after detailed on-the-spot studies of the constraints faced by selected developing countries in establishing and expanding their pharmaceutical industry. The three issues were considered by the UNIDO secretariat as suitable because they could be solved by greater international co-operation. Other problems identified were the prerogative of national policy.

14. The Meeting adopted the following Agenda:

i. Issues recommended for consideration by the First Consultation;

ii. Adoption of the Report of the Meeting.

In the pre-session document ID/WG.317/1, the UNIDO secretariat suggested three issues that might be considered by the First Consultation, namely:

(a) The pricing and availability of intermediates and bulk drugs;

(b) Guidelines for licensing arrangements for the transfer of technology for the basic manufacture of the active ingredients of essential drugs and formulations;

(c) The availability, terms and conditions for the transfer of technology for the manufacture of 25 essential drugs.

The other documents submitted to the Meeting are listed in Annex A.

15. The Meeting adopted the Report of the Meeting at its final session on 27 April 1980. The Meeting was formally closed by Sr. Arsenio Farel, Director-General, Mexican Social Security Institute.

III. ISSUES RECOMMENDED FOR CONSIDERATION BY THE FIRST CONSULTATION

(a) The pricing and availability of intermediates and bulk drugs

16. The Meeting agreed that this issue should be considered at the First Consultation. When preparing the background to this issue, it was suggested that the UNIDO secretariat consider the various factors affecting the price at which intermediates and bulk drugs are sold.

17. The Meeting considered the evidence of disparity in the prices charged for intermediates and bulk drugs contained in UNIDO paper ID/WG.317/1 . The UNIDO secretariat pointed out that the reason for raising this issue was that the high price of intermediates and bulk drugs in relation to the price of finished product affected adversely the economics and feasibility of establishing basic manufacturing and formulating facilities.

18. Participants from developing countries stressed that disparities in prices were sometimes even greater than those shown in the UNIDO report. They felt that the disparity should be much less in order to be reasonable and facilitate the development of basic manufacture and formulation in developing countries. It was further pointed out that where there were many sources of supply, the disparity of prices was much less than when there were only two or three suppliers or where supplies were tied to purchases from the parent company. Furthermore, in one developing country it was indicated that three of its plants established for the manufacture of essential drugs were closed down at present because of the high price of intermediates

19. Participants from developed countries indicated that no-one should be surprised at a very large disparity in prices. Indeed, a uniform set of prices would not be normal since different prices showed that there were a number of different suppliers and that competition existed. These participants also pointed out that the price quoted for any particular sale would depend on the volume of sales, the duration of the contract, the quality of the product and related services including research, the class of customer, specific tender requirements as regards marking, coding, etc., the liability of the supplier, the patent situation in the purchasing country, etc. In addition to these factors, the general market conditions varied so much from country to country that there was nothing surprising in finding differences in prices of the order 1:10.

20. The accuracy of the information presented by UNIDO for a few specific cases was questioned by a few participants from developed countries, and in particular in the case of one product for which prices were quoted for one sole supplier. It was also pointed out that for one other product the price quoted for one country was two years out of date. The UNIDO secretariat informed the Meeting that the information presented was based on quotations received by developing countries. Participants from developing countries confirmed this.

21. Participants from developing countries indicated that it was difficult for them to monitor world prices of bulk drugs and intermediates and to solve the problem of pricing and availability of intermediates and bulk drugs. They further indicated that it might be useful, therefore, that UNIDO prepares and regularly updates a directory of sources of supply of essential drugs and their intermediates in both developed and developing countries, to be circulated among developing countries. Collaboration from the pharmaceutical industry, companies, industry associations and international organizations would be helpful in this respect.

22. In order to avoid the big differences in prices of some basic drugs and their intermediates, participants from developing countries thought it might be useful that a joint committee representing both developed and developing countries, under the auspices of UNIDO, be set up to discuss the sources of supply and pricing scheme of the UNIDO list of essential drugs and the intermediates needed for the production of these drugs . The same participants felt that it would be advisable that the prices agreed upon be stabilised for a certain period of time; the prices set by the committee should be declared by UNIDO to the developing countries.

23. The international pharmaceutical industry and its associations were invited to assist UNIDO in compiling the requested information on sources of supply. However, the representative of the industry from one industrialized country cautioned that the laws affecting the companies which he represented would not allow them to take part in an exchange of information on and discussion of prices.

24. Participants from a few developing countries suggested that market research should be undertaken by the international pharmaceutical industry to ascertain the requirements for intermediates and natural resources especially medicinal plants of developing countries. In order to ensure reliable supplies, developing countries needed to establish plants to serve sub-regional or regional markets.

(b) Contractual arrangements for the production of drugs

25. The Meeting agreed that this issue should be considered at the First Consultation.

26. It was further agreed that this issue would contain two parts, namely:

Part 1: Relevant issues to be taken into account when negotiating a transfer of technology agreement

The following important factors, inter alia, should be taken into account:

i. Health sector structure and health-care delivery system;
ii. Local technical skills and supporting technical infrastructure;
iii. Economies of scale;
iv. Industrial property legislation;
v. Fiscal and other legislation including tariff duties.

Part 2: Preparation of guidelines

Guidelines for licensing arrangements for the transfer of technology for the basic manufacture of the active ingredients of essential drugs and formulations.

27. The agreement on the contents of this issue was reached in the following way. The UNIDO secretariat proposed that the Consultation consider the issues described in Part 2. However, participants from developed countries and the IFPMA felt that this issue had to be broadened.

28. After lengthy discussion, a small working group was established by the Chairman, to elaborate the important factors that had to be considered when negotiating a licensing agreement. The Meeting reviewed and agreed on the five important factors that this working group identified. It then decided that these factors should be considered as the first part of this issue rather than as a separate issue.

29. When preparing the background paper for the First Consultation, the UNIDO secretariat would take into account (a) the points raised in the discussion of this issue and (b) documents already published by UNCTAD and the United Nations' Agencies on technology transfer to developing countries.

30. As an indication of the contribution of developed countries to the transfer of technology to developing countries, the representative of the United Kingdom presented data for the first time drawn from 19 European research-based pharmaceutical companies. This data reviewed the existing position relating to the transfer of technology, training programmes for production, quality control, distribution and storage.

(c) 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

31. The Meeting agreed that this issue should be considered at the First Consultation.

32. The UNIDO secretariat explained that it was proposed that discussion on the above issue relate to an illustrative list of 25 drugs rather than the whole range of pharmaceutical products so that the discussion could be practical. The UNIDO secretariat also explained how the illustrative list of 25 drugs had been prepared (see ID/WG.317/1, paras. 25 and 26).

33. The Meeting generally agreed that the list selected by UNIDO was useful as an illustrative list[1/]. However, before presentation to the First Consultation, UNIDO should update the list in consultation with WHO and developing countries.

1/ In this connection, one participant stressed that medicinal plants and other biological resources are relevant and important resources for the manufacture of some essential drugs and pharmaceuticals. UNIDO should promote transfer and development of the technology needed to manufacture such essential drugs as alternatives to some drugs included in the present UNIDO illustrative list.

34. A number of comments were made related to specific drugs included in the list such as Ethinylestradiol, Bephenium, Resepine, Streptomycin, Methyldopa, Vitamin B_{12} and Blood Fractions. It was suggested that some of these drugs may be replaced by other drugs which are therapeutically to be preferred for primary health care and which require a less sophisticated manufacturing process. It was further pointed out that some drugs on the list were classified as complementary drugs by WHO. In the case of blood fractions, albumin and plasma may be given priority over the other more complex fractions.

35. Some participants felt that (a) immunologicals vaccines and sera and (b) disinfectants and antiseptics should be included in the UNIDO list as recommended by the Second UNIDO Panel Meeting. It was pointed out by UNIDO that they had not been included so far because the technology was already available through WHO and other sources.

36. Bearing in mind the opportunities to acquire technology to produce 25 drugs that already exist, it was suggested that UNIDO compile a directory of sources of technology which give the salient features of the technology. In compiling this directory, account should be taken of the experience of developing countries with these technologies and the terms and conditions they obtained.

37. It was pointed out by the participants from developed countries that the local manufacture of bulk drug substances might lead to higher ex-factory costs. Some of the participants from developing countries pointed out that they might be willing to accept this for reasons of industrialization, foreign exchange savings or other strategic considerations.

IV. WORK THAT MIGHT BE UNDERTAKEN BY UNIDO PRIOR TO THE FIRST CONSULTATION

38. As regards the first issue, namely, "The pricing and availability of intermediates and bulk drugs", the UNIDO secretariat was requested to identify sources of bulk drugs and intermediates for the WHO list of essential drugs[1/] and the UNIDO illustrative list of essential drugs, respectively.

39. Regarding the second issue "Contractual arrangements for the production of drugs", UNIDO was invited by one participant to take note of the recommendation of the Havanna Conference of Heads of State or Government of Non-Aligned Countries that a code on trade, distribution and transfer and development of technology in pharmaceuticals should be prepared. He further suggested that UNIDO should work together with UNCTAD and WHO in drafting such a code and present any results achieved between now and December 1980 to the First Consultation. Some doubts were expressed about the usefulness of this exercise by a participant from a developed country.

40. It was pointed out that the Interregional Meeting held in Cairo in 1979 has asked UNIDO to prepare a model contract for the transfer of technology or at least the essential points to be taken into consideration and the clauses to be included in such a contract. Bearing this point in mind, it was suggested by several participants that a detailed draft be prepared for the First Consultation and be circulated well in advance. The participants from developed countries recommended that UNIDO's treatment of this subject adopt a neutral approach.

41. In connection with the third issue "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", the suggestion was made by a participant from a developing country that UNIDO should establish a task force to prepare a directory of the possible sources of the most up-to-date and reliable technology for the production of essential drugs. This directory should also indicate the terms and conditions for the transfer of such technology.

1/ The Selection of Essential Drugs: Second Report of the WHO Expert Committee. World Health Organization, Technical Report Series 641, 1979.

42. Bearing in mind the need for strategic planning in order to obtain economies of scale, it was suggested that UNIDO, after consultation with the relevant developing countries and regional organizations, should prepare an action programme that proposed which active ingredients can be produced and in which region; the proposals should also indicate how, where and when these active ingredients might be produced. It was suggested that after some time of operation of such projects, UNIDO should review their performance in order to help future projects with the experience gained.

ANNEX A

LIST OF DOCUMENTS

ID/WG.317/1	Issues that might be considered at the First Consultation
CRP. 1	List of Participants
CRP. 2	WHO Position Paper for the UNIDO Preparatory Meeting for the First Consultation on the Pharmaceutical Industry
CRP. 3	UNCTAD's Contribution to Selected Issues in the Pharmaceutical Sector: Note by the UNCTAD Secretariat
CRP. 4	Activities of European Research-based Pharmaceutical Companies in the Third World
CRP. 5	IFPMA Submission to delegates attending the Global Preparatory Meeting for Consultations on the Pharmaceutical Industry

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