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United Nations Industrial Development Organization

Second Panel Meeting of Industrial Experts
on the Pharmaceutical Industry

Vienna 28 February to 3 March 1978

DRAFT REPORT OF THE MEETING *

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PREFACE

1. The Second General Conference of 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 and among developing countries themselves.

2. The evolution of the system of continuing consultations takes place under the guidelines of the Industrial Development Board, UNIDO's governing body. It has decided that consultations should be organized first on industrial sectors and that participants from interested countries should include officials of Governments as well as representatives of industry, labour, consumer groups, etc.

3. In 1977, first consultation meetings were convened by UNIDO on the fertilizer, iron and steel, leather and leather products and vegetable oils and fats industries.

4. The Industrial Development Board decided in May 1977 that it would consider at its next meeting in May 1978 on which two additional industrial sectors consultation meetings would be convened in the biennium 1978 - 1979. In the meantime, UNIDO was asked to continue its initial preparations for convening consultation meetings on the following sectors of industry: petrochemicals, pharmaceuticals, capital goods, agricultural machinery and agro-based industries.

5. The First Panel of [illegible] Experts on the Pharmaceutical Industry was convened from 30 June to 1 July 1977 as a first step in making preparations for the Consultation Meeting. This Panel recommended that a further meeting be held after the first draft of the UNIDO Worldwide Study on the Pharmaceutical Industry had been completed. A summary of the UNIDO Study was, therefore, considered at the meeting.

6. The purpose of the Second Meeting of the Panel of Experts was, therefore, to consider as experts in their individual capacities (a) some topics suggested by UNIDO which might be considered at the Consultation Meeting and (b) the UNIDO Study in draft form.

I. ORGANIZATION OF THE MEETING

7. The Second Meeting of the Panel of Experts on the Pharmaceutical Industry was convened in Vienna, 28 February to 3 March 1978. The meeting was attended by 18 participants from 17 countries and observers from international organizations and consultants, UNIDO task force and staff members; they are listed in Annex - D, E, and F.

9. The meeting was opened by Mr. A. Hacini, Head of the Negotiations Section, which is responsible within UNIDO for the preparation for and organization of consultation meetings.

9. The meeting was chaired by Mr. M.C. Verghese, Head of the Chemical Industries Section, who is Chairman of the task force established within UNIDO to prepare for consultations on the Pharmaceutical Industry.

10. The following agenda was adopted:

- Consideration of the Summary of the Draft UNIDO World-wide Study on the Pharmaceutical Industry;
- The preparation of a national list of drugs to meet local health needs;
- Criteria for selecting drugs from this list suitable for local production;
- Discussion of an initial list of 12 drugs suitable for local production prepared by UNIDO;
- Terms and conditions for the transfer of technology and know-how;
- Co-operation with international pharmaceutical companies;
- Potential areas of co-operation amongst developing countries;
- International organizations and the development of the pharmaceutical industry in developing countries.

11. After discussion by the Panel as a whole, sub-groups were formed to discuss the following topics:

a) on criteria of drugs for production in developing countries

b) on the development of formulation of drugs

c) on the transfer of technology

The full text of the report of these sub-groups, as modified and approved by the Panel, are included as Annexes A, B and C.

II. CONCLUSIONS AND RECOMMENDATIONS

1. The preparation of a national list of drugs to meet local health needs

12. Each country should draw up a national list of drugs covering its major requirements to suit its particular local needs and its policy in the field of health. The model list of essential drugs drawn up by the W.H.O. Expert Committee can serve as a reference in this connection. Based on this national list the items to be procured or manufactured locally can be established; the stage from which such manufacture can be undertaken will depend on the capabilities of the local pharmaceutical industry.

2. Criteria for selecting drugs for local production

13. For selecting drugs from the national list suitable for local manufacture the following list of criteria were agreed by th Panel:

a) the drug is widely used and/or required by the health authorities to treat diseases prevalent in developing countries;

b) its efficacy and safety in the treatment of diseases has been demonstrated and W.H.O. has endorsed its use;

c) the cost per treatment is low enough for the population to afford;

d) there are other special advantages of local manufacture as opposed to imports (cost of transport, stability during transport, availability of raw materials, saving of foreign exchange, etc.);

e) feasibility study of the project indicates that economic production could be ultimately attained including the meeting of regional and inter-regional demands;

f) the manufacturing process is appropriate to conditions prevailing in the country;

g) the know-how for manufacture is available for production whether patented or not.

14. The Panel agreed that the following points should be examined by the Government/parties and others concerned when deciding on local manufacture of a particular drug:

a) patent position of the drug;

b) availability, cost and potential sources of manufacturing know-how;

c) brief description of manufacturing process and flowsheets;

d) lower or late intermediates required;

e) sources of supply of lower or late intermediates as well as basic raw materials and their prices;

f) suggested minimum plant capacity with provision for expansion;

g) investment required;

h) companies already producing the drug in developing countries;

i) a uniform breakdown of unit costs of manufacturing.

3. Modifications to the initial list of 12 drugs for local production prepared by UNIDO in consultation with W.H.O.

15. The Panel examined a list of 12 drugs whose manufacture in developing countries, starting with intermediates or basic raw materials, was deemed desirable by UNIDO after preliminary consultations with some officials of W.H.O. in order to meet the major health needs.[1/]

The Panel agreed that the following drugs were suitable: Analgesics-acetylsalicylic acid, Anti-bacterial drugs-ampicillin, benzyl penicillin, tetracycline, Anti-malarials-chloroquine, primaquine, Anti-tuberculosis drugs isoniazid. It modified the other drugs listed as follows.

1/ See paragraph 91, page 20 for the list of 12 drugs.

16. The inclusion of the analgesic paracetamol and the anthelmintics Mebendazol and piperazine should be reconsidered in consultation with W.H.O. in view of the reported toxic effects.

17. The antibacterial drug procaine benzyl penicillin should be replaced by phenoxymethyl penicillin (oral drug). The antituberculosis drug Rifampicin may be replaced by streptomycin and ethambutol.

18. Additions to the list should be made to include immunologicals, sulfa drugs and disinfectants and antiseptics for medical practice and household use.

19. This list should be considered only as a starting list and if any country desired it can include other items badly needed for the health programmes.

4. Development of formulation of drugs

20. The Panel agreed to the following guideline for the selection of products on which formulation activities could be concentrated in those countries where the pharmaceutical industry was just starting. Bulk drugs should be formulated into dosage forms such as tablets, capsules, ointments, liquid preparations, infusions etc.

a) the medical need should be established by studies on prevalent diseases and be sufficient to justify a relatively large volume of production;

b) in the first phase, pharmaceutical products should be technically easy to produce and the products should have a reasonably wide therapeutic range;

c) in the second phase, more difficult products and those of narrow therapeutic range should be considered;

d) all products should have a good stability, particularly in hot and humid climates.

5. Terms and conditions for the transfer of technology and know-how

21. The Panel discussed the following six methods available for transfer of technology and their advantages and disadvantages:

1. Establishment of subsidiaries by foreign companies
2. Joint ventures
3. Transfer of technology under licence with or without royalties
4. Outright sale of technology
5. Co-operation between developing countries
6. Through United Nations organizations

22. The Panel agreed that transfer of technology for the manufacture of these 12 drugs in developing countries needed to be accelerated and for this purpose one of the six methods listed above might be suitable. Terms and conditions for the transfer of technology were suggested by UNIDO, these were modified and then agreed by the Panel as follows:

a) for drugs on which the patent has expired, the cost of purchasing technology and manufacturing know-how (often expressed in terms of technical fees and royalties on sale) should be at a reasonable rate, appropriate to the product concerned in view of the patent expiry date;

c) for drugs on which the patent has not expired, the cost of buying the technology and manufacturing know-how may be higher; however, the nearness to the end of the patent life should be taken into account;

c) when only supply of know-how for formulation is involved such payments should be reasonable, appropriate to the information supplied;

d) when further stages of manufacture are undertaken within the country, higher payments are admissible;

e) the package of terms and conditions should permit different scales of royalties taking into account the technology involved;

f) the transfer of technology and manufacturing know-how should be as complete as possible in the sense that the developing country should be entitled to existing and new information on the medical effectiveness of the drug, improvements in the manufacturing process made by the licensor, etc.;

g) personnel of the developing country should be trained to manage and operate the production facility and to undertake product information, distribution and product research and development activities;

h) the technology transferred should be adapted to meet local conditions, as and when required, by the supplier of technology collaborating with local expertise of the developing country;

i) where the drug is manufactured from a bulk intermediate the supplier of technology should ensure that the regular quantity of the intermediate is made available at reasonable prices;

j) recognising the desire by many developing countries to develop exports, the terms of such agreements should be established by both parties when negotiating each technology transfer arrangement.

It is recognised that in several countries restrictions on procurement of key ingredients such as intermediates from particular suppliers need not apply. This will depend upon the technological competence of the company concerned and would in any case be a matter of discussion between the interested parties;

k) the supplier of technology should assist the developing country to undertake the production of bulk intermediates within the country in a phased programme so that all or as many stages of production as possible are undertaken within the country.

6. Co-operation with locally owned pharmaceutical companies

24. Limitations of the resolutions mentioned by industry to establish manufacturing facilities in developing countries have to be encouraged for bringing about a real progress. Several resolutions by the Federation of Pharmaceutical Manufacturers' Associations in this connection, need to be examined.

24. The Panel considered the views expressed by the International Federation of Pharmaceutical Manufacturers Association in a statement made at UNIDO's request after the first panel meeting, and noted the conditions which would help to encourage the international pharmaceutical industry to establish manufacturing facilities in developing countries. It was agreed that full text of the IFPMA statement be made available to the Consultation Meeting so that the organization's point of view may be understood.

7. Potential areas of co-operation amongst developing countries

25. Few developing countries have the necessary large market and established chemical industry needed to manufacture a broad range of drugs.

26. Co-operation among the smaller developing countries is therefore essential if a range of drugs and intermediates are to be produced on an economic scale. If these countries could establish a national list of drugs harmonised to the greatest possible extent, establishment of economic size manufacturing facilities within such a group could be facilitated.

27. Establishment of regional pharmaceutical industry development centres could also help promote co-operation in manufacturing and related fields.

28. Assistance from other developing countries who have advanced in the field is valuable as conditions prevailing would be similar and their technology more easily adaptable.

8. International organizations and the development of the pharmaceutical industry in developing countries

29. UNIDO and W.H.O. were urged to support self-sustaining programmes for the development of human skills such as training of pharmacists, chemists, engineers and technologists and setting up of quality control facilities by the industries and governments. The Panel agreed that the co-operation of the international pharmaceutical companies could greatly enhance the programmes' effectiveness.

30. The Panel noted that W.H.O. and UNIDO were also considering the new drugs needed to treat diseases prevalent in developing countries. In this connection, representatives of international pharmaceutical companies present agreed to supply information on the companies pursuing such research and their fields of interest.

31. The Panel also recommended that co-operation be extended to research carried out in this field in developing countries. In particular, there is need to develop a local capability to carry out toxicological studies of new products developed by local research laboratories.

32. The Panel also noted that UNIDO is examining the potential for on-the-spot processing in developing countries of plant products now largely exported in their crude forms. Ways to establish extraction units in developing countries which would increase the value of the exported product need to be examined. In this connection, the production of drugs based on scientific screening of traditional medicines could also be considered as a related topic.

33. To assist developing countries who have no experience in negotiating foreign collaboration agreements, UNIDO should prepare certain guidelines to arrive at reasonable terms of agreement. Similarly guidelines on policy to promote and regulate the development of the Industry should be drawn up to help achieve rapid progress. UNIDO's technological information and advisory service could guide these countries in selecting the most suitable technology.

9. Comments on UNIDO World-wide study of the Pharmaceutical Industry

34. The statistical data presented in the study should be carefully checked against other sources of data. The participants agreed to supply UNIDO with information and data about production, consumption and health expenditures available from their own sources.

35. In view of the large difference in price levels of drugs existing in different countries the use of value terms in expressing consumption might lead to wrong conclusions and has to be used cautiously.

36. The study should provide more information on the contribution of research to the development of the pharmaceutical industry. The more important new drugs discovered in the last 25 years, specially those contributing to the treatment of diseases in developing countries, should be highlighted .

37. Preconditions for establishing a viable pharmaceutical industry and more information on the infrastructural problems connected with distribution and production should be indicated .

38. Based on the study of changing patterns of demands in developing countries authoritative forecasts of pattern of demands for 1985 and 2000 should be given to help developing countries formulate national policies.

39. A forecast in demand should take into consideration that in many developing countries traditional medicine was important for a large percentage of the population.

40. Case studies of developing countries should be examined to determine why in certain countries the industry has made more progress than in others.

41. The study should use its assessment of developing countries requirements to demonstrate how best a viable industry requiring large scale production units can be achieved by expanding medical facilities and hence domestic demand and pooling of demands of neighbouring countries .

III. SUMMARY OF THE DISCUSSION

1. The preparation of a National List of Drugs to meet local health needs.

42. Since the first meeting of the panel of experts on the pharmaceutical industry in June 1977, the World Health Organization (WHO) had published Technical Report Number 615 - "The Selection of Essential Drugs". This Report of a WHO Expert Committee contains a Model List of Essential Drugs (about 200 drugs listed under their generic names). It points out that limited drug lists have the following advantages:

a) Reduction in the number of pharmaceutical products to be purchased, stored, analysed and distributed;

b) Improvement in the quality of drug utilisation, management information and monitoring;

c) Stimulation of local pharmaceutical industries;

d) Assistance to the least developed countries in urgent need of high priority drug programmes to solve their primary health-care problems.

43. Every developing country will have to establish a national list of drugs to meet the real health-needs of the majority of its population. Drugs included in such a list would differ from country to country, depending on many conditions, such as the pattern of prevalent diseases, the type of health personnel available, financial resources, and genetic, demographic and environmental factors, because of the great difference between countries, the preparation of a drug list of uniform general applicability and acceptability is not feasible. Therefore each country should undertake the responsibility of evaluating and arriving at a list of national drugs according to its own policy in the field of health.

44. Having prepared such a list, the method of procurement or manufacture chosen will depend on the stage of development of the pharmaceutical industry in the country.

45. The stages of development of pharmaceutical industry existing in developing countries can be classified into different groups. A broad classification into five groups and steps involved in improving them would be as follows:

Group 1

Countries which have no manufacturing facilities and therefore are dependent upon imported pharmaceuticals in their finished form.

Limited public health services, poor distribution channels.

Steps to be taken:

a) Establish procurement procedures to take advantage of purchasing in large quantities;

b) Develop quality control facilities to ensure quality of drugs purchased;

c) Establish units for repacking of formulated drugs as a training ground to help build the auxiliary industries of packing materials and standardise their production;

d) Set up units for producing infusion solutions and simple formulations in hospital pharmacies or as separate units.

Group II

Countries which are already repacking formulated drugs and are making simple formulations.

Steps to be taken:

a) Establish formulation units to convert bulk drugs into dosage forms such as tablets, capsules, liquid preparations, ointments and infusion solutions;

b) Establish facilities to control quality right from the raw material to the finished product. In addition to set up the requisite organisation frequently to study the stability of the drug. In cases where products fail to meet the specifications they should be recalled from the markets.

Group III

Countries which formulate a broad range of bulk drugs into dosage forms and are starting production of simple bulk from intermediates.

Steps to be taken:

a) Establish multipurpose plants to produce the bulk drugs required for the health programmes by grouping products where production involves similar chemical reactions;

b) Set up units for extraction of active principles from medicinal plants, which grow wild or are cultivated in the country;

c) Set up centres to utilize slaughterhouse by-products, such as the extraction of active principles of glands and organs, to produce catgut, etc.;

d) Set up unit to produce immunologicals both for prophylaxis and treatment.

Group IV

Countries which produce a broad range of bulk drugs from intermediates, and which manufacture some intermediates using local raw materials.

Steps to be taken:

a) Set up units for the production of antibiotics by fermentation;

b) Set up plants for intermediates covering also the needs of the other chemical based industries.

Group V

Countries which manufacture the intermediates required for the pharmaceutical industry and produce plant and equipment required. They also undertake local research in order to develop new products and improve manufacturing processes.

Steps to be taken:

a) Expand the range of intermediates and the volume of production to be able to meet other developing countries' requirements;

b) Expand the production of chemical plant equipment and machinery both for the production of dosage forms and the production of drugs from basic chemicals.

46. The Panel pointed out that there was a need to distinguish clearly between the formulation of drugs and the pharmaceutical chemical industry that is the basic manufacture of fine chemicals or other active ingredients. In the production of these chemicals, a large market was needed; for some products a population of 10 million might justify a production unit but for other chemicals a market of 100 million might be insufficient. The Panel noted that for some pharmaceutical intermediates the three largest countries in Latin America were considering combining their markets to facilitate local production of a range of these intermediates. In fact, it was only countries with a well developed chemical industry that could consider the production of many intermediates from local raw materials.

2. Criteria for selecting drugs from this list suitable for local production

47. The Panel considered the criteria which UNIDO suggested might be used to select drugs suitable for local manufacture from the national list. Some participants felt that if a drug was on the WHO model list of essential drugs, there was no need to consider medical criteria; rather the criteria for local manufacture should be techno-economic ones, such as sufficient demand to make the production unit viable, the availability of raw materials or intermediates, the availability of technology and its degree of complexity, savings in foreign exchange, the investment required and the existing capacities within the country.

48. Participants from developing countries felt that the criteria should not be too restrictive; if the drug was needed by the country in sufficient volume to warrant local manufacture, this was enough justification. The fact that there was over-capacity in the world to produce the drug in question was not relevant as this was often temporary and did not always lead to lower prices of imports. The Panel agreed to the set of criteria listed in Annex A.

3. Discussion of an initial list of 12 drugs suitable for local production prepared by UNIDO

49. UNIDO presented a list of twelve drugs widely used in developing countries and several of them relatively simple to manufacture. This list together with the comments of the Panel on each drug is given in Annex A.

50. It was suggested to add to these some immunologicals, sulpha drugs, disinfectants, oral diabetics and replace rifampicin with streptomycin and ethambuthol. It was agreed to delete rifampicin pending the results of clinical trials which might establish a low-cost treatment suitable for developing countries when used in combination with the cheaper drug isoniazid.

51. Since reservations were expressed on the use of mebendazole, paracetamol and piperazine, UNIDO should refer this matter to WHO for their consideration and advice.

52. UNIDO prepared a background paper containing manufacturing profiles of an economic sized plant for some of the 12 drugs. These profiles contain information on raw material requirements, the process used, equipment used, total investment required and estimated costs of production.

53. The Panel observed that the cost of manufacturing the active ingredients for drugs given in the paper were considerably higher than the price at which the same ingredient could be obtained by importing from developed countries. The decision to support local manufacture of these active ingredients in place of much cheaper imports would therefore need to be supported by Government policy.

54. Some participants favoured a wider list of drugs which should be prepared by the Public Health Authorities of the country. By way of explanation, it was pointed out that the proposed UNIDO list was a starting list containing twelve drugs needed in most developing countries; there was no intention to suggest that local manufacture of these drugs should be started at the same time; norwas there anything to stop a country considering local manufacture of other drugs that were also badly needed in the country.

4. Development of formulation of drugs

55. To undertake only the formulation of pharmaceutical products as distinct from basic manufacture of the twelve drugs discussed above, is a simpler task. The Panel noted that several developing countries have already established a pharmaceutical industry which covers a substantial proportion of the medical needs with drugs formulated locally. This shows that such an industry can be developed in many of the countries which at present consume only imported products.

56. Market research in some African countries has demonstrated that about two thirds of the medicines consumed belong to the following therapeutic groups: antibiotics, analgesics, respiratory products, ophthalmological products, dermatological preparations, vitamins, antidiarrhoeal products, anthelmintics and antimalarials. This research also demonstrated that, in spite of the low per capita consumption of pharmaceutical products, the market is supplied by several thousand different drugs preparations.

57. The Panel agreed to the guide lines for selection of products on which formulation activities might be concentrated; They are described in Annex B.

5. Terms and conditions for transfer of technology and "Know-how"

58. Guidelines should be drawn up by the Panel based on the experience of the experts to help inexperienced countries in negotiating technical collaboration agreements. These guidelines should add momentum to negotiations and help inexperienced countries to make a fair deal even in regard to specific clauses. They should cover technical assistance required during the period of the contract, supply of raw materials and the economic details. The actual technical assistance required by any country will depend on the level of its technical base and those countries which have no experience should ask for supply of more details which should be made available to them and suitable clauses included in the agreement. The ideal agreements will be beneficial to both parties and will help in building up mutual trust and understanding.

59. The developing countries felt strongly that transfer of technology should preferably not include any restrictions on the export markets or sources of import of raw materials which can be supplied by the licenser provide that the eventuality of export and/or terms of export and sources of import in each case was negotiated and agreed upon by licenser and licensee.

60. The Panel discussed the methods available at present for the transfer of technology. Technology and manufacturing know-how could be obtained through the establishment of a subsidiary, a foreign company, a joint-venture, an agreement to manufacture under licence or through outright purchase of technology. Other possibilities for certain drugs were to arrange for the purchase of technology from another developing country or to request UNIDO to use available United Nations funds to purchase the technology for the country.

61. Each method has advantages and disadvantages that have to be weighed by the recipient country. For example, outright purchase of technology might have some financial advantages but it gave the buyer a more limited access to further technological developments; it could only be recommended to countries which had the capability to evaluate the technology and up-date it themselves as required. A subsidiary of a foreign company might have access to all further technological developments but all the benefits would accrue to the foreign owner.

62. The Panel, therefore, considered the joint venture the best method of giving benefits to both sides. The foreign company has a strong and continued interest in the joint venture and will continue to supply information on technological developments from its research. It also shares in the profits of the venture. However, even with such joint ventures, the Panel recommended that the selling price of drugs should be negotiated between the company and the appropriate authorities of the recipient country.

63. For countries which wish to establish a production unit without any foreign investments but wish to benefit from the latest technological developments relating to the drug in question, arrangements to manufacture under licence were suggested with the amount of royalties payable depending on the particular patent situation and other factors.

64. The Panel noted that some developing countries have developed their own technology for production of certain drugs. Arrangements for the transfer of such technology to another developing country had the advantage that the level of production and technology might be more appropriate to local conditions than that obtained from other sources. Such transfer coul be agreed bilaterally or through UNIDO.

65. In case the Governments or other bodies wish to finance the transfer of technology through UNIDO, the extent of involvement of UNIDO will depend on the request of the Government or other bodies to use available United Nations funds for this purpose. On request of Governments and other bodies UNIDO should (a) act as a catalyst by introducing developing countries to companies able and willing to supply technology; (b) advise developing countries on the feasibility of setting up production as a national or regional venture; and (c) provide technological consultancy advisory services with regard to the negotiations, bearing in mind that technological information made available in the negotiations is often confidential.

66. For the list of 12 drugs suggested by UNIDO and amended by the Panel (paragraphs 49 to 51), the Panel agreed that the transfer of technology for the manufacture of these drugs needed to be accelerated. For this purpose one or other of the six methods listed above in paragraph 60 might be suitable. The set of guidelines on terms and conditions for inclusion in the original technical collaboration agreement was agreed; they are described in Annex C.

6. Co-operation with International Pharmaceutical companies

67. Because of the large and growing import bills for pharmaceutical products which developing countries face, they have a strong incentive to save foreign exchange and maximise local employment by local manufacture, which may show considerable savings over the cost of importing finished products. Some developing countries are interested in the production of a drug from basic raw materials, which may further reduce the cost of imports.

68. The cost of production in the developing country may be above that of importing the drug. Even so, from the developing country's point of view, local manufacture may be desirable.

69. A statement by the IFPMA communicated to UNIDO, in response to a request as to what conditions they would suggest to encourage the international pharmaceutical industry to establish manufacturing facilities in developing countries included the following points:

a) protection of industrial property rights in the case of patented drugs;

b) avoidance of excessive control of the selling price of drugs;

c) freedom to transfer dividends and royalties;

d) the government support for, rather than pressure to reduce, the equity held in joint ventures;

e) the freedom to use trademarks promoted in other countries;

f) the adoption of good manufacturing practice by the local pharmaceutical industry and government support to enforce this.

The full report of the IFPMA should be made available to the Consultation Meeting so that the organisation's point of view may be fully understood.

7.- Potential areas of co-operation amongst developing countries

70. Only a few developing countries have the necessary large market and established chemical industry needed to manufacture a broad range of synthetic drugs or antibiotics from local raw materials. For the majority of developing countries, therefore, co-operation with other developing countries will be required if a range of drugs and intermediates is to be produced on an economic scale.

71. This co-operation could be facilitated if the efforts of a group of countries to establish a national list of drugs were harmonised to the greatest possible extent with a view to facilitating the establishment of manufacturing facilities within such a group of countries.

72. Co-operation in developing the pharmaceutical industry could also be strengthened if a range of supporting services were provided by Regional Pharmaceutical Industry Development Centres. Regional centres have been established in Africa and Asia and information on these centres will be supplied to the Consultation Meeting.

8. International Organizations and the development of the Pharmaceutical Industry

73. The Panel recognised that although the establishment of adequate health care programmes in developing countries has attracted considerable international assistance, the assistance needed to establish the infrastructure that is an essential pre-requisite for developing a pharmaceutical industry needed considerably more attention. WHO and UNIDO are discussing ways in which they can co-operate in programmes that concern the development of human skills such as:

- the training of pharmacists, chemists, engineers and technicians;
- the establishment of quality control facilities by Governments and within production units.

It was agreed that the co-operation of international pharmaceutical companies could greatly enhance the effectiveness of any programmes WHO and UNIDO develop in this field.

74. The Panel noted that WHO and UNIDO are also discussing ways in which their joint efforts can promote:

- research and development of new drugs needed to treat diseases prevalent in developing countries
- the local production of drugs produced from plants and other natural products
- the production of drugs based on scientific screening of traditional medicines both for active principles and standardisation.

75. The Panel expressed concern that international pharmaceutical companies were not giving enough attention to research and development of new drugs for diseases prevalent in developing countries. In this connection, the industry representatives present agreed that UNIDO should be supplied with information on the names of companies undertaking such research. The Panel also recommended that co-operation be extended to research carried out in this field in developing countries. In particular, there is a need to develop a local capability to carry out toxological studies of new products developed by local research laboratories.

76. The Panel also noted that several developing countries export plant products from which active ingredients for drugs are extracted in developed countries and that UNIDO is examining the potential for on-the-spot processing in developing countries. Ways to establish extraction units in developing countries which would increase the value of the exported product could be considered at the Consultation Meeting. In this connection, the production of drugs based on scientific screening of traditional medicines could also be considered as a related topic.

77. The Panel were informed of the activies of the UNIDO/WHO/UNCTAD Intersecretariat Task Force on pharmaceuticals and recommended that UNIDO continue to collaborate closely with WHO and UNCTAD in matters concerning their respective fields of competence.

78. It would be useful for many developing countries who have no experience in negotiating foreign collaboration agreements if guidelines for the negotiations of contracts could be drawn up by UNIDO. UNIDO's technological information and advisory service should guide those countries to select the most suitable technology for the country and arrive at reasonable terms of agreement. Guidelines on policy to promote and regulate the development of the Industry should be drawn up to help achieve rapid progress. Country studies on transfer of technology made by UNCTAD (Ceylon India and Senegal) could be used.

9. Comments on UNIDO World-wide study of the Pharmaceutical Industry

79. In presenting a preliminary summary of the world-wide study on the pharmaceutical industry, the UNIDO Secretariat indicated that the study itself has not yet been completed and therefore this summary gives only a brief description of the contents and the main conclusions. The Study will provide an analysis of the past growth of the industry, the present situation and the main factors which will affect its development up to the year 2000.

80. The Panel proposed that some of the statistical data, which were mainly from United Nations sources, be carfully checked against other sources of data. For this purpose, the participants promised to supply UNIDO with their own information and data about production, consumption and health expenditures. Readers should be cautioned about the use of consumption statistics expressed in value terms because of the large difference in price levels prevailing in different countries.

81. The Study might provide more information on the contibution which a high level of research activity has made to the development of the pharmaceutical industry. In this connection, the more important new drugs discovered in the last 25 years should be identified with a view to assessing the contribution made to treating diseases prevalent mainly in developing countries.

82. It was suggested that more emphasis should be put on the pre-conditions for establishing a viable pharmaceutical industry; the need for a national health policy, appropriate medical services, drug legislation including the registration of drugs, quality control facilities and the training of personnel dealing with drug production and distribution. More information on the infrastructural problems connected with distribution of drugs as well as their production was suggested.

83. In view of the derivation of many drugs from plants and other natural sources, the Study should show developing countries which drugs can be manufactured from such locally available raw materials.

84. If the Study is to help developing countries formulate national policy, authoritative forecasts of the pattern of demand for 1985 and 2000 were needed. In this connection, it was suggested that the changing pattern of demand in several developing countries should be studied by UNIDO. In many developing countries, traditional medicine was still important and the use of modern medicine was limited to a small percentage of the population. A forecast of demand would need to take this into account.

85. The Study should make use of case studies of developing countries to determine the reasons why the industry had made more progress than in others.

86. A viable industry requires large-scale production units. The study should, therefore, use its assessment of developing countries' requirements to demonstrate the need for expanding medical facilities and hence the domestic market as well as the pooling of demands of neighbouring countries.

87. Some detailed comments were made on specific topics considered in the Summary. These will be taken into account when the Study is prepared for distribution.

ANNEXURE A

REPORT OF THE SUB-GROUP ON CRITERIA OF DRUGS FOR PRODUCTION IN DEVELOPING COUNTRIES

88. Out of the five groups of developing countries as defined in the UNIDO paper, Group 1 - countries which have no manufacturing facilities and therefore are dependant upon imported pharmaceuticals in their finished form, and Group 2 - countries which have made a beginning by repacking formulated drugs and are making simple formulations, should be assisted to set up formulation facilities specially for making infusion solutions, simple dosage forms such as tablets, ointments and liquid preparations as a first priority. Specially in Group 1 countries units for transfusions and simple formulations should be organized in a semi-industrial scale attached to the hospitals.

89. The sub-group discussed the criteria for selecting drugs and active ingredients for production in developing countries and suggested the following:

a) the drug is widely used and/or required by the health authorities to treat diseases prevalent in the developing countries;

b) its efficacy and safety in the treatment of diseases has been demonstrated and WHO has endorsed its use;

c) the cost per treatment is low enough for the population to afford;

d) there are other special advantages of local manufacture as opposed to imports (cost of transport, stability during transport, avialability of raw materials, saving of foreign exchange, etc.);

e) feasibility study of the project indicates that economic production could be ultimately attained including the meeting of regional and inter-regional demands;

f) the manufacturing process is appropriate to conditions prevailing in the country;

g) the know-how for manufacture is available for production whether patented or not.

90. As regards the technical information which should accompany the listing of each drug, the following points should be examined by the Government/party concerned:

a) patent position of the drug;

b) availability, cost and potential sources of manufacturing know-how;

c) brief description of manufacturing process and flowsheet;

d) plant required and necessary engineering studies;

e) lower or late intermediates required;

f) sources of supply of lower or late intermediates as well as basic raw materials and their prices;

g) suggested minimum plant capacity with provision for expansion;

h) investment required;

i) companies already producing the drug in developing countries;

i) a uniform breakdown of unit costs of manufacturing.

91. In the light of the above, the drugs selected by UNIDO in co-operation with officials of WHO were examined:

Analgesics	acetylsalicylic acid - no comments
	paracetamol - recent reports have indicated toxic effects of this drug and therefore this may need to be re-examined with reference to WHO
Anthelmintic	mebendazole - in the Extra Pharmacopoeia 27th Edition (Martindale) page 1/24 it is mentioned under toxic effects "It is teratogenic in rats and should not be given to pregnant women". In view of this, this may also be re-examined with reference to WHO
Anti-bacterial drugs	piperazine - same remarks as for paracetemol
	ampicillin - no comments
	benzyl penicillin - no comments
	tetracycline - no comments
	procaine benzyl penicillin - this may be replaced by phenoxymethyl penicillin
Anti-malarials	chloroquine - no comments
	primaquine - no comments
Anti-tuberculosis drugs	isoniazid - no comments
	rifampicin - this may be replaced by streptomycin and ethambutol

The sub-group also suggests drugs of the sulpha group should also be included such as sulphacetamide, sulphalimidine, sulphadiazine.

92. The sub-group also suggests that immunologicals relevant to the countries concerned should also be included in the list. The sub-group also recommends that disinfectants and antiseptics are very essential for medical practice and household use in developing countries and, therefore, should be included in the list. An oral antidiabetic which is simple to produce like Tolbutamide should also be included.

ANNEXURE 2

REPORT OF THE SUB-GROUP ON THE DEVELOPMENT OF FORMULATION OF DRUGS

93. Developing countries proposing to establish industry to manufacture finished pharmaceutical products will need to consider the following:

a) A number of developing countries all over the world has already developed pharmaceutical industry and in these substantial proportion of the medical needs are covered by national production. This shows that such an industry can be developed in countries which at present consume only imported products.

b) A market research on some African countries demonstrated that about 65% to 70% of the medicines consumed belong to the following therapeutic groups. 1/

- antibiotics
- analgesics
- respiratory products
- ophtbalmological products
- dermatological preparations
- vitamins
- antidiarrhoeal products
- anthelminthics
- antimalarials

c) The same research demonstrated that in spite of the low per-capita consumption of pharmaceutical products the market is divided in several thousands of specialities.

d) For the same areas, studies on the prevalence of diseases had been already done and this should also be used as the guide-line for selection of products on which production must be concentrated.

e) For successful industrial operation other factor must be considered such as:

i) the medical need should be sufficient to justify a relatively large volume of production;

ii) the pharmaceutical products should be technically easy to produce. More difficult products must be considered for a second phase;

iii) the first examples of products to be considered should have a reasonable wide therapeutic range; those of narrow therapeutic range should be considered for a second phase;

iv) product should have a good stability, particularly in hot and humid climates.

1/ Figures of market research are only indicative and must be revised before choosing products for local preparation.

f) In those developing countries in which pharmaceutical industry already exist industrial protection of different type has been provided by governments. A check list of these protections should be made available to countries intending to industrialize.

g) One starting step could be the simple repacking of imported bulk products.

h) Special technology is required for each products and this should be obtained from appropriate sources. There are several examples of such collaboration within the private sector, and a check list of these examples would be useful.

i) The establishment of a new industry required not only the technology for plant operation but for the whole management including marketing, distribution, quality control, etc. Such technology can be negotiated with companies from countries that have reached the stage IV and V according to UNIDO's classification.

j) Countries interested in pharmaceutical industry must facilitate appropriate transfer of technology.

k) The initiation and expansion of the pharmaceutical industry required a commitment on the part of governments to encourage such developments. Governments policy in the form of a clear strategy with specific targets is a prerequisite for industrial developments in developing countries.

l) Governments should also implement a plan for their own quality control. Until this is achieved, quality control with certification could be performed outside.

m) Full benefit both for the new industry as well as for the country could be obtained if governments delineate a health policy to extend the use of appropriate pharmaceutical products to the majority of the population especially in rural areas.

n) Since in most of the developing countries traditional medicine based especially on the use of medicinal plants covers a large production of the population and as WHO has recommended the encouragement of the rational use of traditional medicine, the new industry could collaborate with governments to achieve this goal.

ANNEXURE C

REPORT OF THE SUB-GROUP ON THE TRANSFER OF TECHNOLOGY

94. The Panel discussed the methods available for the transfer of technology and listed the following:

a) Establishment of subsidiaries by foreign companies
b) Joint ventures
c) Transfer of technology under licence with or without royalties
d) Outright sale of technology
e) Co-operation between developing countries
f) Through UN organisations

95. The various arrangements with overseas companies for the transfer of technology involve different types of advantages and disadvantages to the recipient developing countries and these countries would therefore need to weigh the disadvantages against the advantages involved in the light of their own needs and circumstances.

96. There was unanimous agreement that method "d" is generally the last desirable as it means that the purchaser obtains technology which is dated and may soon become obsolete. The seller has no further interest in the project.

97. The other methods, especially "b" ensure that the seller continues to be associated with the project, has a commercial interest in seeing that it remains successful and also continues to supply information.

Overseas Subsidiaries

98. When subsidiaries are established, the country in which they are situated benefits from the following factors:

a) No equity investment is required
b) Local personnel receive training
c) There is continuous updating of information
d) The firm setting up the subsidiary takes all the risk

When the setting up of a subsidiary is being discussed there should be sufficient flexibility in the arrangements to provide basis for the foreign company.

99. It would be [illegible] that a [illegible] feasibility study to be made by the [illegible] company [illegible] to determine what should be provided in the light of its own views of the market possibilities. There must be sufficient [illegible] venture [illegible] or regional arrangements, [illegible] organized by UNIDO.

100. The Panel [illegible] joint ventures the best method of giving benefits to both sides. The foreign company has a strong and continued interest in the [illegible], and will continue to supply information from its research. It also shares in the profits of the venture.

101. Prices should be [illegible] between the company and the appropriate authorities of the recipient country.

102. For the establishment of both subsidiary and joint ventures the foreign company must have assurance that the local enterprise will not be expropriated once it is established, that its patents and trade marks will be respected and that it will be allowed to transmit reasonable dividends to the parent company.

103. The country in which the subsidiary or joint company is to be established should have the appropriate persons to make use of the technology on a continuous basis.

<u>Licence With or Without Royalties</u>

104. For countries which wish to establish a production unit independently without any foreign investment but wish to benefit from the latest developments relating to the product in question, it is suggested that the amount of royalties [illegible] depend on the particular patent situation.

<u>Outright Sale of Technology</u>

105. This kind of arrangement is not favoured as the buyer has a more limited [illegible] developments except in countries which have the [illegible] and evaluation facilities and to up date the technology with the help of local R and D.

<u>Co-operation between Developing Countries</u>

106. Some developing countries have developed their own technology for production of [illegible]. Governments could agree to make arrangements for transferring the technology between themselves or through UNIDO, if desirable. [illegible] level of production and technology [illegible] infrastructure.

Through UNIDO

107. In case the Governments or other bodies wish to finance the transfer of technology through the country allocation of the UN funds, the extent of involvement of UNIDO will depend on the request of the Government or other bodies.

108. The decision whether to establish subsidiaries or joint ventures or to purchase technology on a licensing and royalty basis will depend on local circumstances prevailing in a country at a given point of time.

109. The availability of raw materials and intermediates was discussed and members of the Panel pointed out that even the most highly developed countries are not entirely self-sufficient.

110. Each country must decide from which stage it must start. An agreement should be reached with the foreign company on the supply of the appropriate technology and intermediates.

The Role of UNIDO

111. On request of Governments and other bodies UNIDO should act as a catalyst by bringing together developing countries and those firms able and willing to supply technology.

112. It should undertake feasibility studies including the possibility of regional agreements for regional manufacturing centres.

113. It should advise developing countries on the feasibility of setting up production particularly when the country involved does not have the resources to evaluate such studies.

114. On request from Governments and other bodies it could put them in touch with potential suppliers of technology and if necessary advise the Governments with regard to the negotiations. If it does so, it would be essential that the confidential technological information made available in the negotiations is not divulged by UNIDO.

List of Drugs suggested by UNIDO for Manufacture

115. The Panel agreed on the list of drugs suggested by UNIDO as amended by the full meeting, as appropriate for developing countries to consider manufacturing. It did not envisage any undue difficulties for such countries to start the manufacture of these drugs. Transfer of technology for the manufacture of these drugs needed to be accelerated and for this purpose one or other of the methods listed above might be suitable under the terms established by UNIDO and agreed to by the Panel. The terms which should be stipulated in the original agreement are as follows:

a) for drugs on which the patent has expired, the cost of purchasing technology and manufacturing know-how (often expressed in terms of technical fees and royalties on sale) should be at a reasonable rate, appropriate to the product concerned in view of the patent expiry date;

b) for drugs on which the patent has not expired, the cost of buying the technology and manufacturing know-how may be higher, however the nearness to the end of the patent life should be taken into account;

c) when only supply of know-how for formulation is involved such payments should be reasonable, appropriate to the information supplied;

d) when further stages of manufacture are undertaken within the country, higher payments are admissible;

e) the package of terms and conditions should admit different scales of royalties taking into account the technology involved;

f) the transfer of technology and manufacturing know-how should be as complete as possible in the sense that the developing country should be entitled to existing and new information on the medical effectiveness of the drug, improvements in the manufacturing process made by the licensor, etc.,

g) personnel of the developing country should be trained to manage and operate the production facility and to undertake product information, distribution and product research and development activities;

h) the technology transferred should be adapted to suit local conditions, as and when required, by the supplier of technology collaborating with local expertise of the developing country;

i) where the drug is manufactured from a late intermediate the supplier of technology should ensure that the required quantity of the intermediate is made available at reasonable prices;

j) recognising the desire by many developing countries to develop exports, the question of such export markets should be considered by both parties when negotiating such technology transfer arrangement.

It is recognised that in several countries the restrictions on procurement of key ingredients such as intermediates from particular sources would not apply. This will depend upon the technological competence of the company concerned and would in any case be a matter of discussion between the interested parties.

k) the supplier of technology should assist the developing country to undertake the production of late intermediates within the country in a phased programme so that all or as many stages of production as possible are undertaken within the country.

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Other UNIDO staff members participating

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Ms. A. Salburg	Sectoral Studies Section International Centre for Industrial Studies

ANNEXURE 5

LIST OF DOCUMENTS

The Steps Involved in Establishing a Pharmaceutical Industry in Developing Countries	ID/WG.267/3
First Draft of the World-wide Study of the Pharmaceutical Industry	UNIDO/ICIS
Guidelines for the Preparation of a National List of Drugs and National Formulary	ID/WG.267/1
Ways of Ensuring Adequate Supplies of Chemical Intermediates required for the Production of Drugs in Developing Countries	ID/WG.267/2
The Selection of Essential Drugs	Technical Report Series 615 WHO Geneva 1977

CONFERENCE ROOM PAPERS

The Development of the Pharmaceutical Industry in Developing Countries: Topics for Discussion	CRP/1
Guidelines for the Transfer of Technology for Establishing the Pharmaceutical Industry in Developing Countries	CRP/2
Regional Pharmaceutical Centres	CRP/3
Co-operation with Developed Countries and International Organizations in Developing the Pharmaceutical Industry in Developing Countries	CRP/4
IFPMA Statement on the Report of the First Panel Meeting of Industrial Experts on the Pharmaceutical Industry	CRP/5
Background Paper: Reports on drugs from the National Drug List which because of their essentiality could be produced in the Developing Countries	CRP/6

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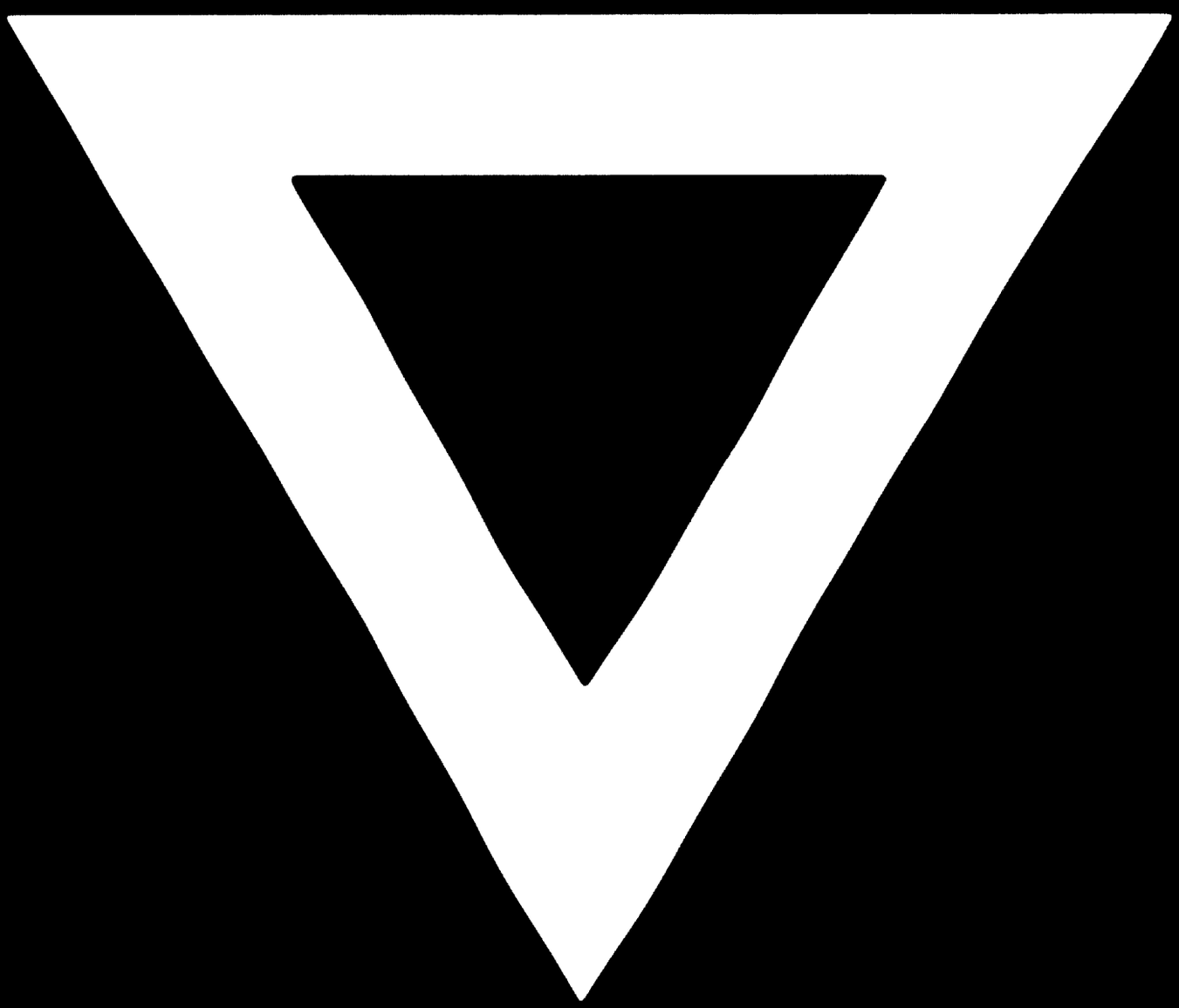

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