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

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United Nations Industrial Development Organization

Second Panel Meeting of Industrial Experts
on the Pharmaceutical Industry

Vienna 28 February to 3 March 1978

REPORT

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Annexes

INTRODUCTION

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 system of continuing consultations takes place under the guidelines of the Industrial Development Board (IDB), the governing body of UNIDO. The IDB 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 IDB 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 Industrial Experts on the Pharmaceutical Industry was convened from 30 June to 1 July 1977 as an initial step in making preparations for the Consultation Meeting. This Panel recommended that a further meeting be held after the first draft of the UNIDO world-wide 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 Panel Meeting of Industrial Experts was to consider as experts in their individual capacities some topics suggested by UNIDO that might be taken up at the Consultation Meeting and 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 from 28 February to 3 March 1978. The Meeting was attended by 18 participants from 17 countries, observers from international organizations and consultants, assisted by a UNIDO task force and staff members; the participants are listed in annexes IV and V.

8. The Meeting was opened by Abdallah 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 Maligil 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:

(a) Consideration of the summary of the draft UNIDO world-wide study on the pharmaceutical industry;

(b) The preparation of a national list of drugs to meet local health needs;

(c) Criteria for selecting drugs from this list suitable for local production;

(d) Discussion of an initial list prepared by UNIDO of 12 drugs suitable for local production;

(e) Terms and conditions for the transfer of technology and know-how;

(f) Co-operation with international pharmaceutical companies;

(g) Potential areas of co-operation among developing countries;

(h) 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) Criteria for production of drugs in developing countries;

(b) Development of formulation of drugs;

(c) The transfer of technology.

The full texts of the reports of these Sub-Groups, as modified and approved by the Panel, are included as annexes I, II and III.

II. CONCLUSIONS AND RECOMMENDATIONS

1. The preparation of national lists 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 health needs and its policy in the field of health. The model list of essential drugs drawn up by the World Health Organization (WHO) 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 on by the 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 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, 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 interregional 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, party or others concerned when deciding on the 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 of 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 WHO

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 WHO, in order to meet the major health needs.[1/]

16. The Panel agreed that the following drugs were suitable:

Analgesics: acetylsalicylic acid

Anti-bacterial drugs: ampicillin, benzyl pencillin, tetracycline

Anti-malarials: chloroquine, primaquine

Anti-tuberculosis drugs: isonoazid

17. It modified the other drugs listed as indicated in the following paragraphs.

18. The inclusion of the analgesic paracetamol and the anthelmintics mebandazol and piperazine should be reconsidered in consultation with WHO in view of the reported toxic effects.

19. The antibacterial drug procaine benzyl penicillin should be replaced by phenoxymethyl penicillin (oral drug). One participant subsequently suggested that oloxacillin available both in oral and injectable forms would be a better substitute for phenoxymethyl penicillin which is becoming increasingly resistant to staphylooocci. The anti-tuberculosis drug rifampicin may be replaced by streptomycin and ethambutol.

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

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

4. Development of formulation of drugs

22. The Panel agreed to the following guidelines 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 in dosage forms such as tablets, capsules, ointments, liquid preparations, infusions, solutions 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;

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

(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

23. 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

24. The Panel agreed that transfer of technology for the manufacture of these 12 drugs in developing countries needed to be acoelerated 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 whioh the patent has expired, the cost of purchasing technology and manufacturing know-how (often expressed in terms of technioal 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 whioh 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 aocount;

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

(d) When further stages of manufacture are undertaken within the country, higher payments are admissable;

(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 oomplete as possible in the sense that the developing country should be entitled to existing and new information on the medioal effectiveness of the drug, improvements in the manufacturing prooess made by the lioensor eto.;

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

(h) The technology transferred should be adapted to suit local ooniditions, as and when required, by the supplier of teohnology oollaborating with local expertise of the developing oountry;

(i) Where the drug is manufactured from a late intermediate the supplier of technology should ensure that the required quantity of the intermediate shall be made available at reasonable prioes;

(j) In view of the desire of many developing countries to develop exports, the inclusion of such export markets should be considered by both parties when negotiating each technology transfer arrangement.

It is recognized that in several countries the restrictions on procurement of key ingredients such as intermediates from particular suppliers need not apply. This will depend on 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 in undertaking 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.

6. Co-operation with international pharmaceutical companies

25. Assistance of the international pharmaceutical industry in establishing manufacturing facilities in developing countries has to be encouraged in order to bring about rapid progress. Several points made by the International Federation of Pharmaceutical Manufacturers Association (IFPMA) in this connection need to be examined.

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

7. Potential areas of co-operation among developing countries

27. Few developing countries have the necessary large market and established chemical industry to manufacture a broad range of drugs. Co-operation among the smaller developing countries is therefore essential if a range of drugs and intermediates is to be produced on an economic scale. If these countries could establish a national list of drugs harmonized to the greatest possible extent, establishment of economic size manufacturing facilities within such a group could be facilitated.

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

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

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

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

31. The Panel noted that WHO and UNIDO were also considering the new drugs needed to treat diseases prevalent in developing countries. Representatives of international pharmaceutical companies present agreed to supply information on the companies pursuing such research and their fields of interest.

32. The Panel also recommended that co-operation be extended to research carried out in this field in developing countries. In particular, there was need to set up and maintain laboratories for toxicological studies in developing countries.

33. The Panel also noted that UNIDO was 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. The production of drugs based on scientific screening of traditional medicines could also be considered as a related topic.

34. To assist developing countries that 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 to achieve rapid progress. The technological information and advisory service of UNIDO could guide these countries in selecting the most suitable technology.

9. Comments on the UNIDO world-wide study of the pharmaceutical industry

35. 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 from their own sources.

36. 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 should be used with caution.

37. 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, especially those contributing to the treatment of diseases in developing countries, should be highlighted.

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

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

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

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

42. The study should use its assessment of the needs of developing countries to demonstrate how best a viable industry requiring large-scale production units can be achieved by expanding medical facilities and hence domestic demand and by pooling the demands of neighbouring countries. A study of five selected developing countries to identify sources of raw materials for the manufacture of 20 essential drugs will serve as a guide to other developing countries which can undertake similar studies to determine if the industry can be self-sustaining.

III. SUMMARY OF THE DISCUSSION

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

43. Since the First Meeting of the Panel of Experts on the Pharmaceutical Industry in June 1977, 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 is pointed 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 use, management information and monitoring;

(c) Stimulation of local pharmaceutical industries;

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

44. Each 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.

45. After the preparation of such a list, the method of procurement or manufacture chosen will depend on the stage of development of the pharmaceutical industry in the country.

46. The Panel noted that in a paper prepared for the Meeting, the UNIDO secretariat classified the stages of development of the pharmaceutical industry existing in developing countries into five broad groups:

Group I. Countries that have no manufacturing facilities and therefore are dependent on imported pharmaceuticals in their finished form; countries with limited public health services and poor distribution channels.

Steps to be taken:

(a) To establish procurement procedures to take advantage of purchasing in large quantities;

(b) To develop quality control facilities to ensure quality of drugs purchased;

(c) To establish units for repacking formulated drugs as training to help to build the auxiliary industries of packing materials and to standardize their production;

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

Group II. Countries that are already repacking formulated drugs and are making simple formulations.

Steps to be taken:

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

(b) To establish facilities to control quality from the raw material to the finished product. In addition, to set up the requisite organization frequently to monitor the stability of the drug. In cases where products fail to meet specifications, they should be recalled from the market.

(For five years UNIDO has been training industrial pharmacists at the State University of Ghent, Faculty of Pharmaceutical Sciences, giving preference to candidates from countries belonging to these groups of countries. This training makes it possible for Group I and II countries to start and run such semi-industrial units with the help of these trained personnel.)

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

Steps to be taken:

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

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

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

(d) To set up a unit to produce immunologicals both for prophylaxis and treatment.

Group IV. Countries that produce a broad range of bulk drugs from intermediates and that manufacture some intermediates using local raw materials.

Steps to be taken:

(a) To set up units for the production of antibiotics by fermentation;

(b) To set up plants for intermediates also covering the needs of the other chemical-based industries.

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

Steps to be taken:

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

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

47. 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 Amerioa were considering combining their markets to facilitate local production of a range of these intermediates. In fact, only countries with a well-developed chemioal industry could consider the production of many intermediates from local raw materials.

2. Criteria for selecting drugs from this list suitable for looal produotion

48. The Panel considered that the criteria suggested by UNIDO 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-eoonomic 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 exshange, the investment required and the existing oapacities within the country.

49. Participants from developing countries felt that the criteria should not be too restrictive; if the drug was needed by the country in suffioient volume to warrant local manufacture, this was enough justifioation. The fact that there was over-capacity in the world to produce the drug in question was not relevant since 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 I.

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

50. UNIDO presented a list of 12 drugs widely used in developing countries several of which were relatively simple to manufacture. This list together with the comments of the Panel on eaoh drug is given in annex I.

51. It was suggested to add to these immunologicals, sulpha drugs, disinfectants, oral diabetics and that rifampicin be replaced by streptomycin and ethambuthol. It was agreed to delete rifampioin pending the results of clinical trials whioh might establish a low-oost treatment suitable for developing countries when used in combination with the cheaper drug isoniazid. One partioipant has subsequently suggested that cloxacillin would be a better substitute for phenoxymethyl penioillin.

52. Since reservations were expressed on the use of mebendazol, paracetamol and piperazine, UNIDO should refer this matter to WHO for its consideration and advice.

53. 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.

54. 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 it 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.

55. 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 12 drugs needed in most developing countries. The intention was not to suggest that local manufacture of these drugs should be started at the same time; nor was 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

56. The Panel agreed that to undertake only the formulation of pharmaceutical products as distinct from the basic manufacture of the 12 drugs discussed above was a simpler task. The Panel noted that several developing countries had already established a pharmaceutical industry that covered a substantial proportion of the medical needs with drugs formulated locally. This showed that such an industry could be developed in many of the countries which at present consume only imported products.

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

58. The Panel agreed to the guidelines for the selection of products on which formulation activities might be concentrated. These are described in annex II.

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

59. 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 give momentum to negotiations and help inexperienced countries to make a fair deal even in regard to specific clauses. They should cover the technical assistance required during the period of the contract, the 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 that have no experience should ask that more details be made available to them and that suitable clauses be included in the agreement. The ideal agreements will be beneficial to both parties and will help in building up mutual trust and understanding.

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

61. 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 lioence 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.

62. Each method had 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 that had the capability to evaluate the technology and to up-date it as required. A subsidiary of a foreign oompany might have access to all further teohnologioal developments but this form had certain disadvantages from the developing country's point of view.

63. The Panel, therefore, oonsidered that the joint venture was 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 price of any necessary materials provided by one partner should be the subject of careful negotiation.

64. For countries wishing to establish a production unit without any foreign investment but at the same time wanting 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.

65. The Panel noted that some developing countries had developed their own technology for the 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 could be agreed bilaterally or through UNIDO.

66. 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 for United Nations funds for this purpose. On the 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 advisory services with regard to the negotiations, bearing in mind that technological information made available in the negotiations is often confidential.

67. For the list of 12 drugs suggested by UNIDO and amended by the Panel, the Panel agreed that the transfer of technology for the manufacture of these drugs needed to be accelerated. For this purpose any one of the six methods listed above might be suitable. The set of guidelines on terms and conditions for inclusion in the original technical collaboration agreement was approved; they are described in annex III.

6. Co-operation with international pharmaceutical companies

68. Because of the large and growing import bills for pharmaceutical products faced by developing countries, they have a strong incentive to save foreign exchange and to maximize local employment by local manufacture, which may allow 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. 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) Government support for, rather than pressure to reduce, the equity held in joint ventures;

(e) Freedom to use trade marks promoted in other countries;

(f) 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 organization's point of view might be fully understood.

7. Potential areas of co-operation among developing countries

70. Only a few developing countries have the necessary large market and established chemical industry 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 harmonized 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 recognized that although the establishment of adequate health care programmes in developing countries had attracted considerable international assistance, the assistance needed to establish the infrastructure that was an essential prerequisite for developing a pharmaceutical industry needed considerably

more attention. WHO and UNIDO are discussing ways in whioh they can co-operate in programmes that concern the development of human skills such as:

(a) Training of pharmacists, chemists, engineers and technicians;

(b) 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 were also discussing ways in which their joint efforts could promote:

(a) Research and development of new drugs needed to treat diseases prevalent in developing countries;

(b) Local production of drugs produced from plants and other natural products;

(c) Production of drugs based on scientific screening of traditional medicines both for active principles and standardization.

75. Some members of 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. Other members expressed concern that the attitude of certain developing countries to patents and trade marks gave little encouragement to the international pharmaceutical industry to continue their efforts in this field. 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 oountries. In particular, there was a need to set up and maintain laboratories for toxicologioal studies in developing countries.

76. The Panel also noted that several developing countries exported plant products from which active ingredients for drugs were extracted in developed oountries, and that UNIDO was examining the potential for on-the-spot processing in developing countries. Ways to establish extraction units in developing countries that would increase the value of the exported product oould be oonsidered at the Consultation Meeting. The production of drugs based on scientifio screening of traditional medicines oould also be oonsidered as a related topio.

77. The Panel was informed of the aotivities of the UNIDO/WHO/UNCTAD Inter-secretariat Task Foroe on pharmaceutioals and recommended that UNIDO oontinue to oollaborate closely with WHO and UNCTAD in matters conoerning their respective fields of oompetenoe.

78. It would be useful for many developing countries that had no experience in negotiating foreign collaboration agreements if guidelines for the negotiations of contracts were drawn up by UNIDO. The technologioal information and advisory service of UNIDO should help those countries to select the most suitable technology for the country and to 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. Studies on the transfer of technology to certain developing countries made by UNCTAD were also mentioned.

9. Comments on the 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 had not yet been completed and that it therefore gave 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 that 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 carefully 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 expenditure. 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 contribution that a high level of research activity has made to the development of the pharmaceutical industry. 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, authorative forecasts of the pattern of demand for 1985 and 2000 are needed. 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 in some 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 and the pooling of demand of neighbouring countries. UNIDO should identify the sources of raw materials in five selected developing countries for the manufacture of 20 essential drugs which will serve as a guide to other countries as well to undertake a similar study and examine how far the industry could be self-sustaining.

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.

Annex I

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 I countries, which have no manufacturing facilities and therefore are dependant upon imported pharmaceuticals in their finished form, and Group II countries, whioh have made a beginning by repacking formulated drugs and are making simple formulations, should be assisted in setting up formulation facilities especially for making infusion solutions, simple dosage forms such as tablets, ointments and liquid preparations as a first priority. In particular, in Group I oountries units for transfusions and simple formulations should be organized on a semi-industrial scale and attached to the hospitals.

89. The Sub-Group discussed the oriteria for selecting drugs and active ingredients for production in developing oountries and suggested the following:

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

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

(o) That the cost per treatment is low enough for the population to afford;

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

(e) That a feasibility study of the project indicates that economic production could be ultimately attained including the meeting of regional and interregional demand;

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

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

90. As regards the technical information that should accompany the listing of each drug, the following points should be examined by the government/party oonoerned:

(a) Patent position of the drug;

(b) Availability, oost and potential sources of manufacturing know-how;

(o) Brief description of manufacturing process and flowsheet;

(d) Plant required and neoessary 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;

(j) 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:

Drug	Comments
Analgesics	acetylsalicylic acid - no comments
	paracetemol - 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 1724, under toxic effects, it is stated: "It is teratogenic in rats and should not be given to pregnant women". Accordingly, 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[2]
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 that drugs of the sulpha group should be included such as sulphacetamide, sulphadimidine, sulphadiazine.

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[2] One participant subsequently has suggested that a better replacement would be cloraxallin which is available in both oral and injectable forms and is effective against penicillinase-producing microbes.

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

Annex II

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 points:

(a) A number of developing countries all over the world have already developed the pharmaceutical industry and in these countries a 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 produots;

(b) A market research on some African countries demonstrated that about 65% to 70% of the medicines consumed belong to the following therapeutic groups. 3/

Antibiotics

Analgesics

Respiratory products

Ophtalmologioal products

Dermatological preparations

Vitamins

Anti-diarrhoeal products

Anthelminthics

Anti-malarials;

(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 guideline for selection of products on which production must be concentrated;

(e) For successful industrial operation other factors 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 produoe. More difficult products must be considered for a second phase;

(iii) The first examples of products to be considered should have a reasonably wide therapeutic range; those of narrow therapeutio range should be considered for a seoond phase;

(iv) Products should have a good stability, particularly in hot and humid olimates;

3/ Figures of market researoh are only indicative and must be revised before ohoosing produots for looal preparation.

(f) In those developing countries in which pharmaceutical industry already exists industrial protection of a different type has been provided by governments. A check-list of such 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 product 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 requires not only the technology for plant operation but also for the whole management including marketing, distribution, quality control etc. Such technology can be negotiated with companies from countries that have reached stage IV and V according to the classification of UNIDO;

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

(k) The initiation and expansion of the pharmaceutical industry requires a commitment on the part of governments to encourage such development. Government 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 proportion 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.

Annex III

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 United Nations organizations.

95. The various arrangements with overseas companies for the transfer of technology involve different types of advantages and disadvantages to the recipient developing countries. 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 least desirable since 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 a viable basis for the foreign company.

99. It would be advisable for the overseas company to make an economic feasibility study and to determine what shall be provided in the light of its own views of the market possibilities. There must be sufficient potential to justify the venture, if necessary by regional arrangements, possibly organized by UNIDO.

100. The Panel considered joint ventures 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 from its research. It also shares in the profits of the venture.

101. Prices should be negotiated 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 personnel to make use of the technology on a continuous basis.

Licence with or without royalties

104. For countries wishing to establish a production unit independently without any foreign investment but wanting to benefit from the latest developments relating to the drug in question, it is suggested that the amount of royalties agreed to should depend on the particular patent situation.

Outright sale of technology

105. This kind of arrangement is not favoured since the buyer has a more limited access to further technological developments, except in countries having technical and evaluation facilities and the capability to update the technology with the help of local R and D.

Co-operation between developing countries

106. Some developing countries have developed their own technology for production of certain drugs. Governments could agree to make arrangements for transferring the technology between themselves or through UNIDO, if desirable. This approach has the advantage that the level of production and technology will be more appropriate to their infrastructure.

Through UNIDO

107. In oase the governments or other bodies wish to finance the transfer of teohnology through the country allocation of United Nations 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 looal circumstances prevailing in a country at a given point of time.

109. The availability of raw materials and intermediates was disoussed 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 whioh stage it must start. An agreement should be reached with the foreign oompany 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 oatalyst by bringing together developing countries and those firms able and willing to supply technology.

112. UNIDO should undertake feasibility studies including the possibility of regional agreements and regional manufaoturing centres.

113. UNIDO should advise developing oountries on the feasibility of setting up produotion particularly when the country involved does not have the resouroes to evaluate such studies.

114. On the request of governments and other bodies UNIDO oould put them in touoh with potential suppliers of teohnology and, if neoessary, advise with regard to negotiations. If it does so. it would be essential that the oonfidential teohnological information made available in the negotiations not be divulged by UNIDO.

List of drugs suggested by UNIDO for manufaoture

115. The Panel agreed on the list of drugs suggested by UNIDO, as amended by the full meeting, as appropriate for developing oountries to consider manufaoturing. It did not envisage any undue difficulties for such countries to start the manufacture of those drugs. Transfer of technology for the manufaoture of

these drugs needed to be aooelerated and for this purpose anyone of the six methods listed might be suitable under the terms established by UNILO and agreed to by the Panel. The terms that 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 oountry, higher payments are admissible;

(e) The package of terms and oonditions should admit different soales 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 medioal effeotiveness 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 researoh and development activities;

(h) The technology transfered should be adapted to suit looal conditions, as and when required, by the supplier of technology collaborating with looal expertise of the developing oountry;

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

(j) In recognition of the desire by many developing oountries to develop exports, the inclusion of such export markets should be oonsidered by both parties when negotiating each teohnology transfer arrangement. (It is recognized that in several countries the restriotions on proourement of key ingredients such as intermediates from partioular suppliers need not apply. This will depend on the technologioal oompetenoe of the oompany concerned and would in any case be a matter of discussion between the interested parties.);

(k) The supplier of teohnology should assist the developing country in undertaking the production of late intermediates within the oountry in a phased programme, so that all or as many stages of produotion as possible are undertaken within the oountry.

Annex IV

MEMBERS OF THE PANEL OF INDUSTRIAL EXPERTS

Country	Name	Organisation, address
Argentina	A. COMIN	Director Comisión Directiva Cámara Argentina de Especialidades Medicinales (FIFARMA) Cangallo 525, 8° piso Buenos Aires
Belgium	A. HEYNDRICKX	Head Department of Toxicology State University of Ghent Hospitaalstraat 13 B-9000 Ghent
Ecuador	P. NARANJO	Professor of the University Ambassador of Ecuador to the Soviet Union Gorojovski Pereulok 12 Moscow, Union of Soviet Socialist Republics
Egypt	A. ABOULENEIN	Chairman of the Board Managing Director Chemical Industries Development Company Pyramids Avenue Giza, Cairo
France	P.A. DUMAS	Directeur Général des Opérations Pharmaceutiques Françaises Rhône Poulenc Santé 22, avenue Montaigne F-75360 Paris, cedex 8
Germany, Federal Republic of	M.P. TIEFENBACHER	Director Member of the Board of the Pharmaceutical Division HOECHST AG Postfach 800320 Mainstrasse 169 D-6230 Frankfurt/Main 80
Guyana	D.M. DENN	Chairman Task Force on Interregional Project on Economic and Technical Co-operation among Developing Countries in the Pharmaceutical Sector c/o Ministry of Foreign Affairs Georgetown

Country	Name	Organisation, address
Iran	S. SHAFAI	Managing Director Daroopakhsh Pharmaceutical Company Bashomayoon Teheran
Mexico	A. FERNANDEZ HERNANDES	Director General National Chamber of Industry of Chemical Pharmaceutical Laboratories Avenida Cuauhtemoc 1481 Mexico City 13, D.F.
Pakistan	M. AHMAD	Chairman Federal Chemical and Ceramics Corporation Ltd P.O. Box 5570 N.E.C. Building, 15th floor Moulvi Tamizuddin Khan Road Karachi
Poland	S. MIRENSKI	Deputy Director CIECH Polfa Division P.O. Box 271 Jasna 12 PL-00950 Warsaw
Republic of Korea	H. KIM	Managing Director International Operations Seoul Pharmaceutical Company Ltd P.O. Box 313 Kwang Hwa Moon Seoul
Sri Lanka	L.G. JAYEWARDENE	Chairman State Pharmaceutical Corporation P.O. Box 1757 75 Sir Baron Jayatilake Mawatha Colombo
Sweden	S.V. WAHLQVIST	Deputy Managing Director Aktiebolaget Astra AB (ASTRA) S-151 85 Södertälje
Switzerland	E. VISCHER	Member Executive Committee Ciba-Geigy Ltd Basel
	A. HERROG	Secretary General INTERPHARMA Basel

Country	Name	Organization, address
Tunisia	M. EL FEKIH	Pharmacein Directeur de la Pharmacie Centrale de Tunisie Avenue Charles Nicolle Tunis
United Kingdom of Great Britain and Northern Ireland	S.M. PERETZ	Chairman Cyanamid of Great Britain Ltd P.O. Box 7 Fareham Road Gosport Hampshire PO13 0AS
United States of America	P.G. [illegible]	Director Business Development Merck, Sharp and Dohme International P.O. Box 2000 Rahway, New Jersey 07065

Consultants

M. FALCOZ
Pharmacienne
[illegible]

T.D. WHITTET
Chief Pharmacist
Department of Health and Social Security

United Nations Conference on Trade and Development

A. MAISLISCH
Economic Affairs Officer
Transfer of Technology Division

Annex V

UNIDO STAFF MEMBERS RESPONSIBLE FOR PREPARING FOR CONSULTATIONS ON THE PHARMACEUTICAL INDUSTRY

Members of the UNIDO Internal Task Force

Chairman	M.C. Verghese Head Chemical Industries Section Industrial Operations Division
Vice-Chairman	R.J. Line Negotiations Section Division of Policy Co-ordination
Secretary	B. Shah Negotiations Section Division of Policy Co-ordination
Members	H. Koenig Agro-Industries Section Industrial Operations Division
	A. Niklovios Sectoral Studies Section International Centre for Industrial Studies
	H. Molina Investment Co-operative Programme Office Industrial Operations Division
	A. Toheknavorian-Asenbauer Chemical Industries Section Industrial Operations Division
	K. Venkataraman Development and Transfer of Technology Section International Centre for Industrial Studies

Other UNIDO staff members participating

A. Macini	Head Negotiations Section Division of Policy Co-ordination
E. Aguilar	Development and Transfer of Technology Section International Centre for Industrial Studies
A. Salburg	Sectoral Studies Section International Centre for Industrial Studies

Annex VI

LIST OF DOCUMENTS

ID/WG.267/1 — Guidelines for the preparation of a national list of drugs and national formulary
UNIDO secretariat

ID/WG.267/2 — Ways of ensuring adequate supplies of chemical intermediates required for the production of drugs in developing countries
UNIDO secretariat

ID/WG.267/3 — The steps involved in establishing a pharmaceutical industry in developing countries
UNIDO secretariat

ID/WG.267/5 — Reports on drugs from the national drug list which because of their essentiality could be produced in the developing countries
C.N. Chari in co-operation with the secretariat of UNIDO

UNIDO/ICIS — First draft of the world-wide study of the pharmaceutical industry

World Health Organization. The selection of essential drugs. Geneva, 1977. (Technical report series 615)

Conference room papers

CRP 1 — The development of the pharmaceutical industry in developing countries: topics for discussion

CRP 2 — Guidelines for the transfer of technology for establishing the pharmaceutical industry in developing countries

CRP 3 — Regional pharmaceutical centres

CRP 4 — Co-operation with developed countries and international organizations in developing the pharmaceutical industry in developing countries

CRP 5 — IFPMA statement on the report of the First Panel Meeting of Industrial Experts on the Pharmaceutical Industry

CRP 6 — Background paper: reports on drugs from the national drug list which because of their essentiality could be produced in the developing countries

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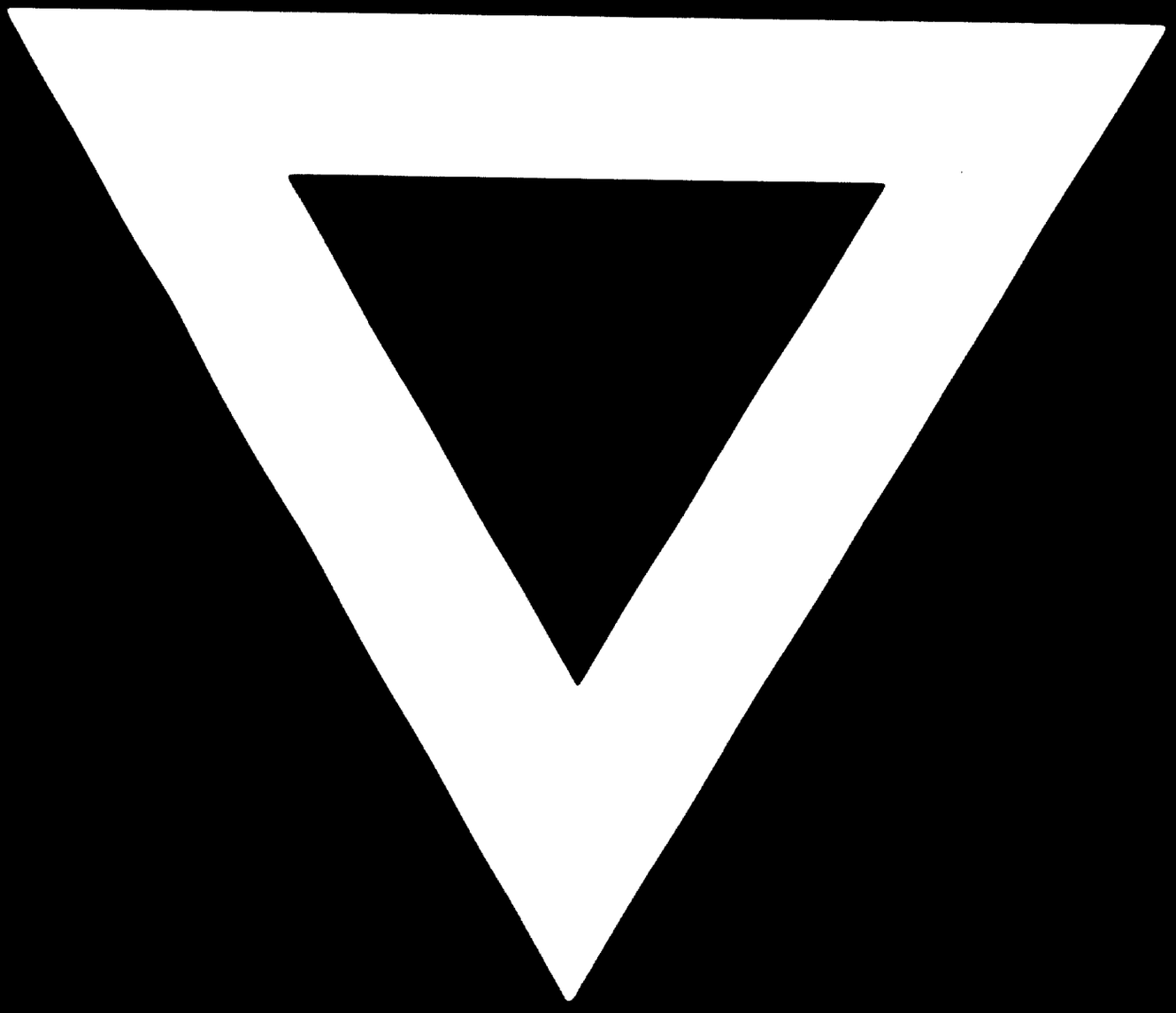

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