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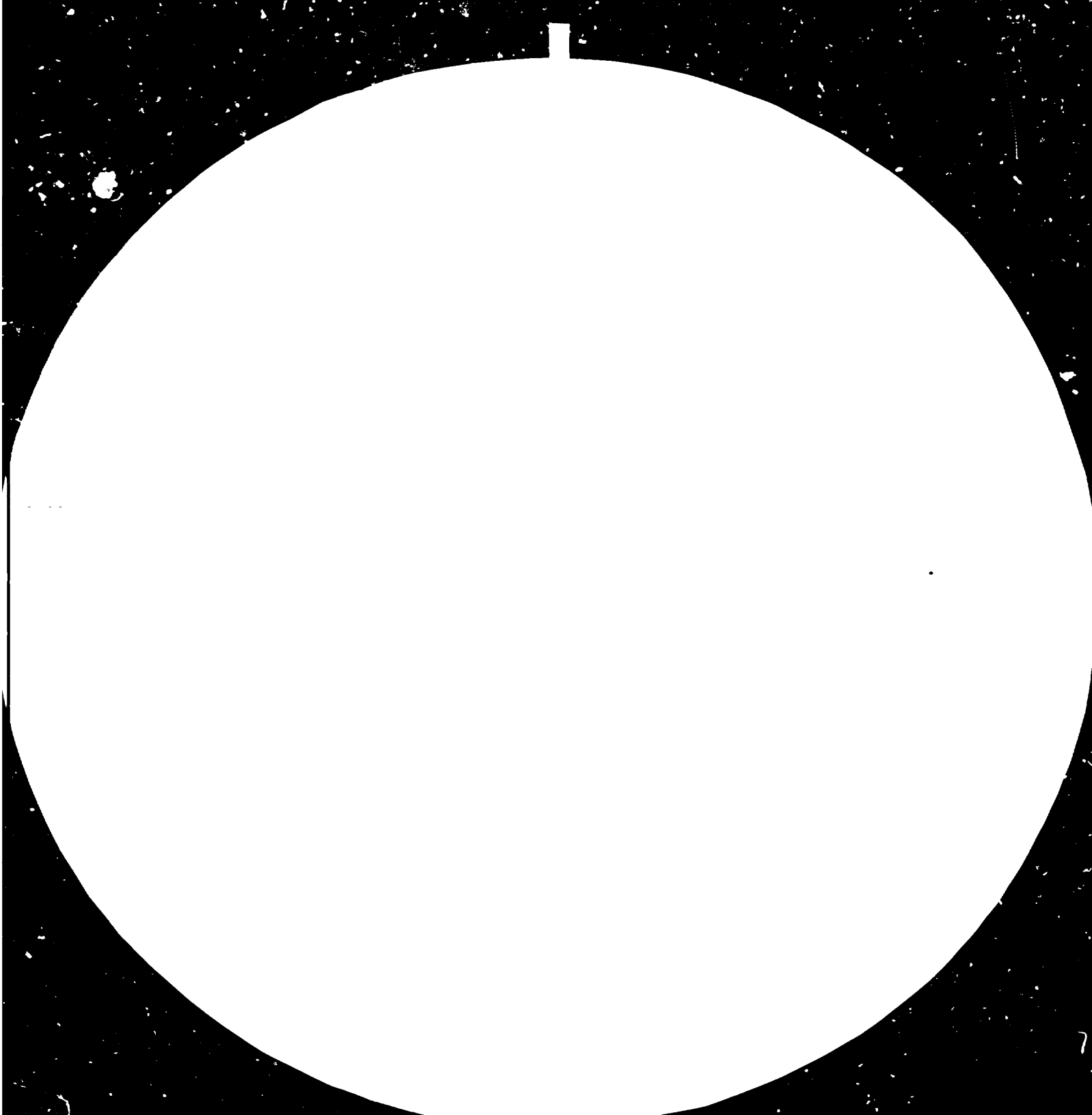
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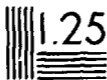
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Resolution test chart showing various line patterns and numerical values.

Resolution test chart showing various line patterns and numerical values.

Resolution test chart showing various line patterns and numerical values.

Resolution test chart showing various line patterns and numerical values.

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UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

Meeting of the Committee of
Experts on Pharmaceuticals
Paris, 11-13 October 1982

Draft Report *

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PREFACE

The Second General Conference of the United Nations Industrial Development Organization (UNIDO), held at Lima, Peru, in March 1975, recommended that UNIDO should include among its activities a system of continuing consultations between developed and developing countries with the object of raising the developing countries' share in world industrial output through increased international co-operation.^{1/}

The General Assembly, at its seventh special session in September 1975, in its resolution 3362 (S-VII), decided that the System of Consultations called for by the Lima Declaration and Plan of Action should be established at global, regional, interregional and sectoral levels,^{2/} and that UNIDO, at the request of the countries concerned, should provide a forum for the negotiations of agreements in the field of industry between developed and developing countries and among developing countries themselves.

The System of Consultations has been established under the guidance of the Industrial Development Board. Having decided in May 1980 to establish the System of Consultations on a permanent basis, the Board in May 1982 adopted the Rules of Procedure^{3/} according to which the System of Consultations is to operate, including its principles, objectives and characteristics, notably:

- The System of Consultations shall be an instrument through which the United Nations Industrial Development Organization (UNIDO) is to serve as a forum for developed and developing countries in their contacts and consultations directed towards the industrialization of developing countries;^{4/}
- The System of Consultations would also permit negotiations among interested parties at their request, at the same time as or after Consultations;^{5/}

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

^{2/} Official Records of the General Assembly, Seventh Special Session, Supplement No. 1, para. 3.

^{3/} The System of Consultation (P1/84)

^{4/} P1/84, para.1

^{5/} Ibid, para. 3

- Participants of each member country should include officials of Governments as well as representatives of industry, labour, consumer groups and others, as deemed appropriate by each Government;6/
- Each Consultation Meeting shall formulate a report, which shall include conclusions and recommendations agreed upon by consensus and also other significant views expressed during the discussions.7/

The First Consultation on the Pharmaceutical Industry was convened in Estoril, Portugal, from 1 to 5 December, 1980.8/ As a follow-up of the First Consultation UNIDO convened a Round Table Meeting on the Pharmaceutical Industry in Mohammedia, Morocco, from 2 to 3 December, 1981.9/ As recommended by the First Consultation, the Committee of Experts on the Pharmaceutical Industry met in Paris, France, from 11-13 October 1982. The names of the participants are listed in Annex I.

6/ Ibid, para. 23

7/ Ibid, para. 46

8/ Report of the First Consultation on the Pharmaceutical Industry, ID/259

9/ Report of the Round Table Meeting on the Pharmaceutical Industry.PC.33

I. ORGANIZATION OF THE MEETING

Opening of the Meeting

1. The Meeting was opened by Mr. A. Hacini, Deputy Director, Division of Policy Co-ordination, Head, Negotiations Branch, UNIDO. In his inaugural address, Mr. Hacini explained the background to the Meeting and more specifically the objectives and the tasks assigned to the Committee by the First Consultation on the Pharmaceutical Industry and the Round Table Meeting on the Pharmaceutical Industry in Mohammedia. He hoped that the documents presented for this meeting would stimulate discussion so that a constructive outcome could be achieved. These are in no way designed to inhibit any other ideas that may lead to the solution of the issues.

He thanked the Government of France on behalf of the Executive Director of UNIDO for hosting this meeting.

2. Mr. A. Lewin, Director for the United Nations and International Organizations and the Ministry of External Relations, Paris, France, then addressed the meeting. He made a reference to his long association with the United Nations and UNIDO, going back to 1975 when the Lima Plan of Action was drawn. He emphasized the importance of the Meeting and hoped that its results would be far-reaching towards achieving the goal of industrialization of developing countries. He wished success to the meeting and expressed thanks to the Executive Director of UNIDO for his decision to hold the meeting in Paris.

Election of Officers

3. Mr. Hacini thanked Mr. Lewin for his address. He once again emphasized that the mandate for the meeting was with the participants and the issue to be discussed is primarily that of the developing countries. He proposed Dr. Gerard Garrido, Peru, to act as Chairman; and Mr. Ernst Vischer, Switzerland, to act as Vice-Chairman of the meeting. He said that both Dr. Garrido and Mr. Vischer have had a long association with UNIDO meetings on the pharmaceutical industry and are well acquainted with procedures as well as the issues. This proposal was unanimously agreed to.

4. Dr. Garrido briefly addressed the participants and expressed his thanks for his election as Chairman of the meeting and stressed the need for co-operation of the participants for solving the tasks assigned to them.

Documentation

5. The documents distributed to the participants are listed in Annex II.

Adoption of the Report

6. The report of the meeting was adopted on 13 October, 1982.

II. CONCLUSIONS AND RECOMMENDATIONS

7. Bearing in mind the aim to arrive at prices for intermediates which are in reasonable relationship with the cost of bulk drugs, negotiations on the supply and the prices of bulk drugs or intermediates should be conducted between suppliers and purchasers based on mutual acceptance.

8. The quantitative requirements of the interested developing countries can be assessed and indicated to the producers. Following negotiations between purchasers and suppliers and based on long-term contractual agreements, the producers should arrange for the production of these intermediates and bulk drugs, and ensure their supply to developing countries at reasonable and mutually acceptable prices.

9. The Committee recommended that UNIDO, in collaboration with the producers from developed and developing countries, and assisted by consultants and experts with industrial knowledge and experience, should undertake a study which should provide non-confidential reference information relevant to the transfer of technology for the manufacture of intermediates and bulk drugs, taking into account technical aspects, such as level of production, magnitude of investment, inputs, infrastructure, etc. Such studies could significantly aid individual developing countries in bilateral negotiations for transfer of technology. The Indicative list of non-confidential reference information required for conducting study (Annex III) may be considered as the necessary background for such a study.

10. Particular attention must be paid to the specific problems of the least developed countries which are still at the first stage of their pharmaceutical development. For these countries, the problem of availability and quality control of bulk drugs and formulations including vaccines at mutually acceptable conditions and prices, as recommended by UNIDO, is of crucial importance.

11. The recommendations made during the First Consultation on the Pharmaceutical Industry, Lisbon, 1-5 December 1980 (page 7, para. 4-5) regarding the transfer of technology for the manufacture of essential intermediates and bulk drugs were noted. (Document ID/259)

III. REPORT ON THE ISSUE - SUMMARY OF DISCUSSION

12. The UNIDO secretariat clarified the constitution of the Committee of Experts on Pharmaceuticals: specially emphasizing that the participants present represented the pharmaceutical industry, including those who are concerned with the production of one or more chemical intermediates related with the nine essential drugs under discussion.

13. The System of Consultations was explained in general, which is an important tool for discussing the ways and means of achieving the Lima target. It was pointed out that the development of the pharmaceutical industry is essential to achieve these goals which have important human and social aspects. The three issues affecting the development of this industry

as endorsed by the First Consultation are:

1. Availability and pricing of bulk drugs and their intermediates;
2. Contractual arrangements; and
3. Transfer of technology for the manufacture of essential drugs.

14. The criteria used for the selection of the UNIDO illustrative list of 26 essential drugs were explained. The summary of recommendations of the First Consultation on the Pharmaceutical Industry convened in 1980 were recapitulated.

15. The secretariat highlighted the main features of the Issue I of the Consultation, which would be under discussion by the Committee:

- (a) There was a disparity between the prices of the bulk drugs and their intermediates.
- (b) The prices of intermediates were a constraint on the production of bulk drugs in the developing countries.
- (c) Non-availability of technology for the production of essential bulk drugs and their intermediates.

16. The pricing scheme which was presented at Lisbon was a mechanism for the evaluation of the relationship between the cost of intermediates and the cost of producing the bulk drugs.

17. It was stressed that the scheme had been used as a possible tool by UNIDO to analyse the impact of the prices of intermediates on the cost of manufacture of bulk drugs; and the scheme should in no way be interpreted as a formula to arrive at fixed prices for intermediates.

18. The UNIDO secretariat and consultants made a detailed presentation on document UNIDO/PC.52. It was pointed out that the study reconfirms the conclusions reached earlier at Lisbon that:

- (a) The costs of intermediates have a direct impact on the cost of production of bulk drugs.
- (b) The updating of technology will lead to greater cost efficiencies in the production of these drugs.

19. The Chairman then invited comments from the participants. The following observations were made:

- A representative from an industrialized country commented that there was general recession in world economy and chemical and pharmaceutical industries were no exception to this. Profitability was lower than it had been before. Governments are making efforts to control social expenses including health-related expenditures, although there is a difference from country to country.

- Seven to eight years ago there was heavy investment in the chemical industry. Large capacities were built up which are unused today and that has resulted in temporarily cheaper prices. It was expressed that such a situation was not expected to last long.

- A representative from a developing country commented that similar economic difficulties were faced by developing countries.

- One delegate from a developing country observed that the document revealed that in two cases, namely: Ethambutol and Isonizid the prices of intermediates had fallen, yet the international prices of bulk drugs had not. Since there is a direct relationship between the costs of intermediates and prices of bulk drugs manufactured from them, a clarification was requested.

- A participant from an industrialized country remarked that the document illustrated the experience of one country only and may not be applicable to other developing countries.

- A few representatives from industrialized countries commented that a generalized method for establishing relations between prices of intermediates and bulk drugs could neither be found nor would it be helpful, therefore discussion should be concentrated on specific drugs and intermediates and in a more comprehensive manner, taking into account factors like investment, return on capital, R and D etc., with the understanding that developing countries are prepared to take higher local cost than those incurred in industrialized countries.

- It was also pointed out that social and political factors play an important role. Model experiments carried out in accordance with principles referred to above could serve as useful input for the Second Consultation.

- A number of representatives from developing countries stressed that there should be a formula available to establish relations between prices of intermediates and bulk drugs.

- A representative from an industrialized country commented that any such formula would not take process improvement into account and experience of his country has shown that fixed ratio between the price of bulk drugs and dosage form has prevented reduction in prices in his country. However, he acknowledged that such formula is useful to show the existence of the problem but not to solve the same.

- A representative from a developing country commented that three main constraints on the development of the pharmaceutical industry in developing countries are those identified by UNIDO in the First Consultation. He felt that pricing is a temporary problem and the crucial issue is availability of appropriate technology for bulk drugs and intermediates. He suggested three possible strategies for solving the problem, namely -

- (a) Competitive purchasing coupled with buying technology;
- (b) Co-operation between developing and industrialized countries and TCDC in the form of joint ventures or joint technology development;
- (c) Self-development of developing countries by local R and D facilities.

- Responding to the observation of one participant as to the fall in prices of intermediates not being reflected in the prices of the bulk drugs, the secretariat stated that it had not been possible for it to trace any clear reasons for this phenomenon.

- One of the participants also observed that some of the intermediates required for the manufacture of bulk drugs are available from a number of sources and do not pose a serious problem. However, intermediates with limited sources of supply need particular attention and co-operation from some developed countries so as to improve their economic availability at such mutually acceptable terms and conditions which would assist the developing countries in successful production of bulk drugs. Similarly some of these bulk drugs which in fact are mainly used in the developing countries were found to have limited sources of supply, and co-operation of developed countries was needed to make such drugs available at reasonable prices to the developing countries.

- A few participants from developing countries noted with concern that the experience of some of the developing countries which had established facilities for manufacture of certain bulk drugs that the same drugs were supplied by the developed countries at extremely low prices which had no relationship to the prices at which their intermediates were made available. This situation had posed problems and difficulties in the developing countries in continuing their production.

- On this a participant from developed countries commented that such a situation is not unusual in the economic world and it happens also in other countries, sectors, etc., from time to time.

- Another participant from developed countries commented that, in his opinion, discussions should be based on facts and figures.

20. The UNIDO document UNIDO/PC.51 "Directory of Sources of Supply of 26 Essential Bulk Drugs, their Intermediates and some Raw Materials" and its' Addendum I were then presented. The Directory was compiled in accordance with the recommendations of the First Consultation on the Pharmaceutical Industry and the Round Table Meeting held in Morocco.

21. The secretariat explained that the Directory is a first step towards assisting developing countries in obtaining their requirements of pharmaceuticals at the best possible prices and on most suitable delivery schedules. UNIDO treats this first version of the Directory as a draft; and will therefore appreciate the contribution of the Committee to make it more accurate and comprehensive.

22. A mathematical concept presented in UNIDO Document PC.51/Addendum I on costing is also attached to the Directory, which may be applied by industrial managers and purchasers in the developing countries to evaluate prices.

23. The Chairman then invited comments on the Directory from the Committee. The following observations were made:

- There was a general appreciation of the Directory which was considered to be very useful by several participants.

- It was suggested that the Directory would require periodic updating. It could also include indicative prices. Another suggestion made was to distinguish the manufacturers from suppliers, which was accepted. There was one suggestion that suppliers be excluded, as manufacturers could be a better source, but this was not favoured by others who felt that on occasion buyers had to depend on suppliers.

- Suggestions were also made with reference to certain specific entries in the Directory such as Blood and Blood fractions etc.

- It was suggested by several participants that the Directory should indicate pharmacopoeial references relating to sources of supply. It should also indicate storage requirements, particularly for heat-sensitive substances.

- Referring to document PC.51 Addendum 1, one participant commented that this document was dangerous because users may arrive at prices which are not attainable in the market. He proposed that the factors condensed in variables ΔM and C_{0j} should be listed for better understanding.

24. The secretariat appreciated the comments made by the participants and stressed again that the Directory was a draft and suggestions to improve same are most welcome. It was also explained that names of manufacturers/suppliers were compiled from information received through the courtesy of IFPMA, national associations and direct contacts with manufacturers in the developing countries. The secretariat informed that after the final version of the Directory is approved, data will be stored on computers which would enable regular amendments and perhaps annual or, biennial revisions. The intention is to publish the directory annually or biennially without indicative prices since these might become outdated during short periods of time. However, the secretariat expressed the intention to collect information on indicative prices which can be given to developing countries upon request. Some participants from developed countries expressed serious reservations regarding the benefits of such an exercise.

25. The secretariat also welcomed the suggestion by a participant from a developed country for setting up centralized procurement systems and long-term contractual arrangements, as these ideas were in line with earlier recommendations made by the secretariat. The secretariat mentioned that accuracy of the Directory will be checked by writing to the listed manufacturers and requesting confirmation.

26. In response to the last point, the secretariat pointed out that the primary intention of document PC.51/Addendum 1 is to describe the method used in arriving at the desirable prices given in document PC.52. Variables C_{0j} and ΔM are complex and represent the sum of elements (e.g. in the case of chloroquine $C_{0j} = C_1 + C_2 + C_3 + C_4$). Conclusions drawn with the use of this scheme are justified only if the data used for the calculation are correct and represent the techno-economic standards of the process described.

27. After extensive discussions on the various aspects of the issue before the Committee, long deliberations and a comprehensive analysis, a draft proposal of recommendations consisting of three parts, was placed before the Committee of Experts for consideration. The final conclusions and recommendation consisting of five parts (paragraphs 7-11) are on page 5 of this report.

ANNEX I

LIST OF PARTICIPANTS

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ANNEX II

LIST OF DOCUMENTS

1. First Consultation Meeting on the Pharmaceutical Industry, Lisbon, Portugal 1-5 December, 1980. Report ID/259
2. Pricing and Availability of Bulk Drugs and their Intermediates, 1980. ID/WG.331/4
3. Background Paper for Discussion on Availability, Pricing, and Technology of Essential Drugs. UNIDO/PC.14
4. Report of the Round Table Meeting on Development of Pharmaceutical Industry. UNIDO/PC.33
5. Directory of Sources of Supply of Bulk Drugs, their Intermediates and some Raw Materials. Addendum. UNIDO/PC.51
UNIDO/PC.51/Add.1
6. Availability, Pricing and Technology of Essential Drugs and their Intermediates. UNIDO/PC.52

ANNEX III

INDICATIVE LIST OF NON-CONFIDENTIAL REFERENCE INFORMATION REQUIRED FOR
CONDUCTING STUDY

1. Name of Product/Intermediate
2. Availability of Product/Intermediate
3. Chemical Flowsheet, non-confidential
4. Chemical Conversion Factors and/or Yields
5. Informative Prices of (Chemical) Inputs
6. Total Conversion Costs
 - Utilities)
 - Energy)
 - Salaries and Wages)
 - Depreciation) upon developing countries' information
 - Maintenance)
 - Overheads)
7. Fixed Capital Requirements; percentage of hard currency required;
local requirement
8. Minimum Economic Scale
9. Environmental Considerations
10. Labour Safety Regulations
11. Special Factors Affecting Present Process Economics (confidential)
12. Infrastructure Required
13. Skilled Personnel Required
14. Type of Technology Transfer (Joint Venture, Lump-Sum Arrangement, Licensing)
15. In case of lump-sum arrangement, the extent to which the producer is
willing to provide assistance such as plant design information; training,
demonstration, etc.
16. Indication of any specific condition.

