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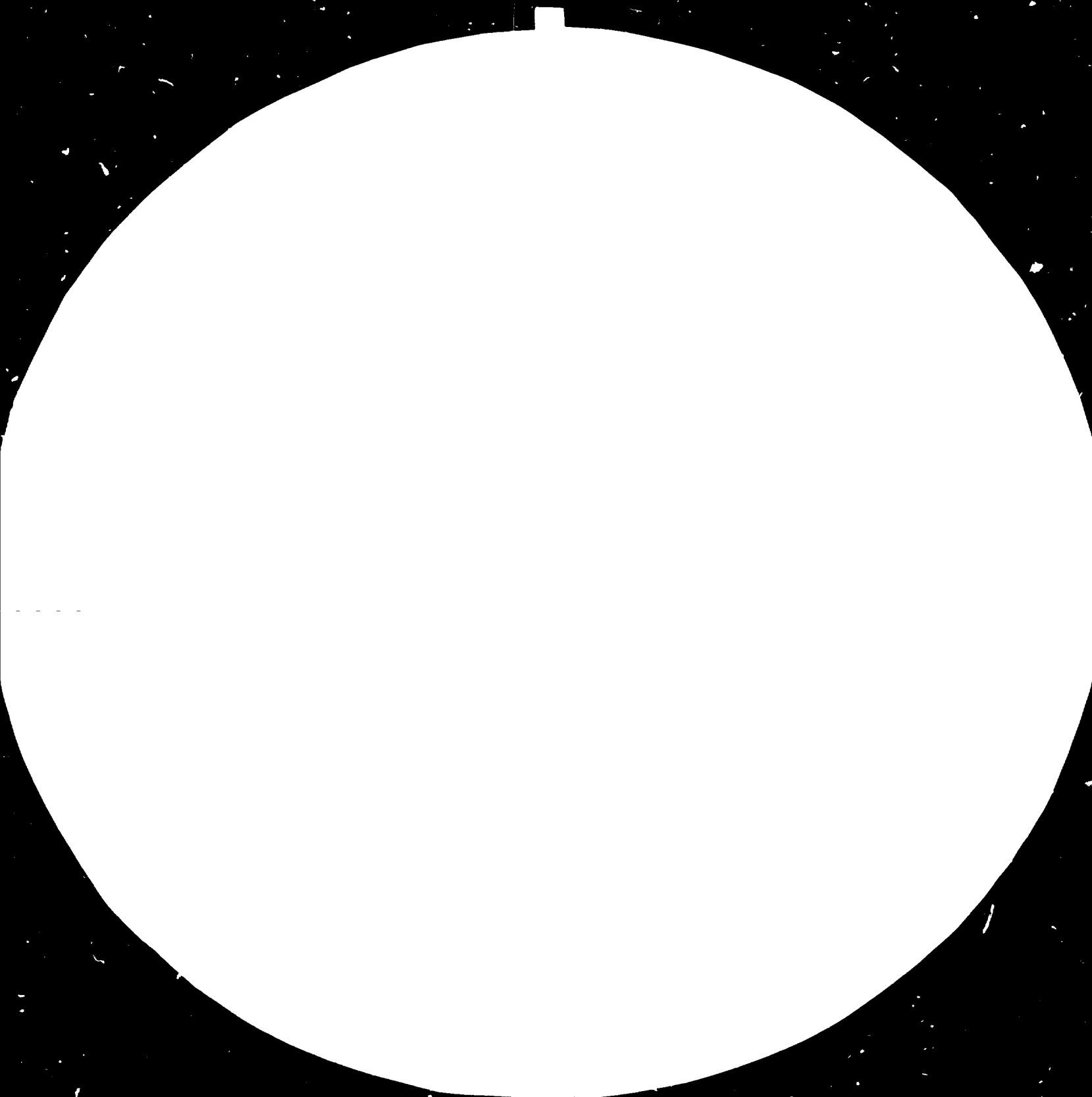

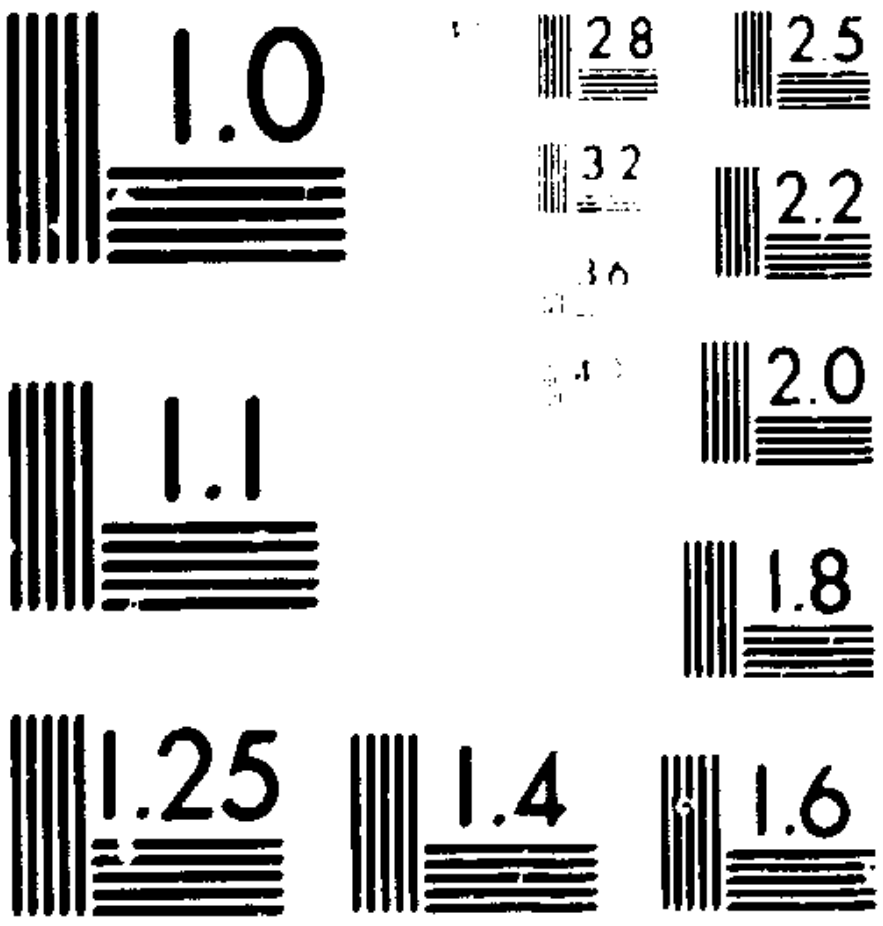

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CONTRACTUAL ARRANGEMENTS FOR THE PRODUCTION OF DRUGS

Background Paper

prepared by
the UNIDO Secretariat

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INTRODUCTION

1. The First Consultation on the Pharmaceutical Industry recommended that UNIDO, in co-operation with an ad-hoc panel of experts selected on the basis of equitable geographic distribution, prepare a document, complete with the necessary background notes on various terms, conditions and variations thereof that could be included in contractual agreements.

2. The First Consultation also recommended that UNIDO should undertake a detailed study on relevant issues to be taken into account when negotiating transfer of technology agreements, considering the experience of developed countries.

3. As follow-up to the above recommendations, UNIDO convened a Round Table meeting on the Development of the Pharmaceutical Industry at Mohammedia, Morocco in December 1981, to advise UNIDO on the preparation of the contractual agreements, the composition of the ad-hoc panel of experts and the study on relevant issues for negotiating transfer of technology agreements.

4. Thereafter, the Ad-hoc Panel of Experts was convened twice in Vienna, Austria in December 1982 and April 1983 respectively, to discuss and complete the three types of contractual agreements, and assist in the implementation of the study. Further, the Ad-hoc Panel recommended the preparation of two additional documents within this issue, and three additional reference studies, one of which was completed. The overall presentation of the issue is given at the end of this paper.

5. The study on relevant issues for negotiating transfer of technology agreements considering the experience of developed countries was carried out by a consultant selected in collaboration with the industry.

I. ROUND TABLE MEETING ON THE DEVELOPMENT OF THE PHARMACEUTICAL INDUSTRY

6. The Round Table Meeting was convened at Mohammedia, Morocco, from 2 to 3 December 1981. It was attended by 22 participants from 15 countries and the industry. The conclusions and recommendations of the meeting were the following (report: UNIDO/PC.33).

7. The UNIDO should prepare a document on contractual arrangements based on the following guidelines:

a) be primarily addressed to parties negotiating transfer of technology agreements;
b) constitute an operational tool for enterprises in developing countries;
c) draw attention to particular problems faced by developing countries in this field, particularly by least developed countries;
d) duly consider the main factors that hamper the successful transfer of technology and the development of the pharmaceutical industry in developing countries.

8. In the preparation of the document the following main principles should be taken into account:

(a) Transfer of technology should contribute to the identification and solution of economic and social problems related to the production and use of pharmaceuticals in developing countries, with an aim at substantially improving, at adequate costs and quality, the availability of essential drugs in developing countries;

(b) The parties to a transfer of technology agreement should be responsive to the health, drug, industrial and other relevant policies of the receiving country, including import substitution, development of technical skills, promotion of local innovation, etc.;

(c) Licensing agreements should contain fair and responsive terms and conditions, including payments, and be no less favourable for the recipient than the terms and conditions usually applied by the supplier or other reliable sources for similar technologies under similar circumstances;

(d) The agreement should, in particular,

(i) ensure the absorption of technology transferred by local personnel;
(ii) allow the use, as far as possible, of locally available materials and services;
(iii) facilitate and, in any case, do not restrict the adaptation and further development of technology received;
(iv) include adequate guarantees for the performance of the parties obligations;
(v) provide full information on the characteristics of the technology and drugs to be manufactured, specially in respect of possible hazards and side effects;
(vi) do not contain unjustified restraints on the recipient's use of the technology.

9. The Panel of Experts to be convened by UNIDO should pay particular attention to the preparation of terms and conditions, variations thereof and background notes relating to agreements for the manufacture of intermediates and bulk drugs. This should be without prejudice to considering the other types of arrangements as described in UNIDO document PC/19. The already large experience of developing countries in agreements for the formulation of dosage forms should be adequately considered when dealing with arrangements for the transfer of technology for that purpose.

10. Among other items to be including in such agreements, the Panel should give special attention to the following:

- supply of intermediates and other major raw materials;
- transfer of improvements;
- conditions of remunerations;
- guarantees;
- use of the technology after the expiration of the agreement;
- export of products;
- training of local personnel;
- confidentiality.

11. The document should also identify the restrictive clauses to be excluded from technology transfer agreements.

12. Advice on composition of ad-hoc panel experts for contractual arrangements

The ad-hoc panel should be as small as possible and not more than 12 in number. There should be equitable geographical distribution with at least one representative from a country at an early stage in pharmaceutical industrialization. The panel should include individuals with experience as licensors and licensees and with legal and technical knowledge. They should, if possible, have had practical up-to-date knowledge and experience of transferring technology to developing countries from either developed or other developing countries.

13. UNIDO detailed study (See paragraph 3 of First Consultation Meeting)

The UNIDO secretariat needs to undertake a detailed study of relevant issues to be taken into account when negotiating transfer of technology agreements incorporating the experience of developed countries. Document PC.19 needs to be revised and expanded to cover these matters. This study should also include the factors that need to be considered before entering into final transfer of technology negotiations, e.g. market studies, economic feasibility studies availability of technical infrastructure, etc. Emphasis should be given to the necessity of evaluating the efficiency of the particular technology under consideration.

II. MEETINGS OF THE AD-HOC PANEL OF EXPERTS ON CONTRACTUAL ARRANGEMENTS IN THE PHARMACEUTICAL INDUSTRY

14. The First meeting of the Ad-hoc Panel of Experts was convened in Vienna, Austria from 15 to 17 December 1982. The Second Meeting of the Ad-hoc Panel was convened in Vienna from 25 to 29 April 1982. The list of the Ad-hoc Panel members is given in Annexures A and B.

FIRST MEETING OF THE AD-HOC PANEL OF EXPERTS: (report: ID/WG.385/4)

A. Summary of discussions

15. The UNIDO Secretariat clarified the consitution of the Ad-hoc Panel of Experts; specially emphasizing that the participants represented the pharmaceutical industry, including those concerned with the transfer of technology, both in developing and developed countries.

The Secretariat highlighted the main features of issue 2 of the First Consultation and the documents for the meeting were introduced. In this presentation, the recommendation of the First Consultation was recalled as well as the recommendations of the Round Table Meeting. It was stated that the documents covered the transfer of technology for the production of bulk drugs/intermediates and for the production of formulations.

The documents on bulk drugs considered (i) arrangements for licensing and setting up of a plant and (ii) preliminary aspect for a turnkey plant (in this case only the obligations of the licensor/contractor have been considered). These documents were presented to cover not only different situations that arise in the practice, but also to cater for the capabilities and wishes of the licensee/purchaser to undertake the coordination and other responsibilities when setting up a plant.

The content, criteria and technical aspects taken into account on the preparation of the documents were explained. Efforts have been made to achieve balanced and fair obligations and compensations for the parties.

16. A few participants suggested that discussions may be started with the document "Arrangements for the Transfer of Technology for the Manufacture of Bulk Drugs and Intermediates" - as it was considered that the topic covered in this document was of major importance to developing countries.

A participant from a developed country appreciated the document but commented that transfer of technology was a difficult matter. Mutual incentives were prerequisites for any talk on the transfer of technology. Some aspects such as laws, population, economic growth, etc. must be looked into first.

17. Another participant felt that the above aspects were connected with another recommendation of the First Consultation, i.e. preparation of a study on the "relevant topics to be taken into account when negotiating the transfer of technology agreements", by taking into account the experience of developed countries.

18. The Secretariat appreciated the remarks and informed the participants that this topic was being discussed with the IFPMA, in order to define the terms of reference in connection with the above study. Following a short discussion on the matter, it was agreed to discuss the study in a working group to be nominated by the Ad-hoc Panel. The working group reported to the Panel that the IFPMA will do its best to provide by the middle of January 1983 the background material to prepare the terms of reference for this study.

19. Commenting on the document, a participant from a developed country observed that the presentation of the document appeared to be a model form of contract and this could misguide the readers.

Another participant suggested avoiding the formulation of specimen clauses. Some participants from developing countries expressed that

speciment clauses contained in the document were very useful for parties without experience in negotiations, and that they should remain as drafted in the document.

20. After extensive discussions on the topic, and in order to clarify the nature of the document, the panel proposed to change its title to read as "Items which could be incorporated in contractual arrangements for the transfer of technology for the manufacture of those bulk drugs/intermediates included in UNIDO's illustrative list" and to include the following paragraphs:

(a) page 4, as the first paragraph:

"This document includes items which could be incorporated in Contractual Arrangements, while negotiating transfer of technology for the manufacture of those bulk drugs and intermediates included in the UNIDO illustrative list."

(b) page 5, before paragraph starting "It is obvious that...":

"It should be noted here that the illustrative clauses provided in this document are included as examples that could be used to achieve transfer of technology. These clauses should not be construed as being exhaustive or covering all possible situations that can arise in transfer of technology."

(c) moreover, the Panel agreed to substitute the word "specimen" wherever it appears, for the word "illustrative". In addition, it recommended to insert as a footnote (indicated after the expression "illustrative clauses") the phrase: "see page 5," paragraph as referred in (b) above.

(d) to be added on page 5 item (iii) that read "the practices which are generally accepted in international licensing and trade" are the words "particularly in developing countries".

21. Finally, the participants went very briefly through the remaining documents and recommended that these should be revised, amended and expanded in order to keep the spirit generated while reviewing the document on the production of bulk drugs/intermediates.

3. Conclusions and recommendations

22. The Ad-hoc Panel requested UNIDO to convene another meeting for [illegible]9 April 1983 to discuss the documents on formulation and setting up of plant.

23. It is also recommended that more participants from the least developing countries should be present at the subsequent meeting.

It was agreed that it was necessary that these participants attending this meeting should also be present in the subsequent meetings of the Panel.

24. The participants from developing and developed countries agreed to forward to UNIDO by the middle of January cases on transfer of technology so that the results of such transfers and experience could be brought to the attention of the Second Consultation as requested by the First Consultation Meeting.

25. To facilitate the preparation of the study on "relevant topics to be taken into account when negotiating transfer of technology agreements taking into account the experience of developed countries", the representative of IFPMA agreed to submit the curriculum vitae of two or three experts to assist UNIDO on this task and an indicative list of terms of reference for the study.

SECOND MEETING OF THE AD-HOC PANEL OF EXPERTS: (report: UNIDO/PC.62)

C. Summary of discussions

26. The Secretariat briefly submitted to the consideration of the Ad-hoc Panel the following documents:

- Items which could be included in Licensing Arrangements for the Transfer of Technology for the Formulation of Pharmaceutical dosage forms.
- Items which could be included in Contractual Arrangements for the Setting up of a Plant for the Production of Bulk Drugs (or Intermediates) included in UNIDO illustrative list.

The Secretariat explained that the document relating to Licensing Arrangements for the production of Bulk Drugs (and Intermediates) has been revised taking into account the comments and recommendations made during the first meeting of the Ad-Hoc Panel.

27. Concerning the document "Licensing Arrangements for the formulation of dosage forms", the Secretariat indicated that the revision included the following amendments:

a) The introduction of the document was substantially reduced;

b) The scope of the document was broadened in order to cover the situation where a new formulation unit is to be established, in addition to the hupothesis where new products are added to existing lines of production;

c) Each item was completed with technical background notes, where appropriate;

d) The general recommendations of the Ad-Hoc Panel were also considered wherever relevant.

28. Regarding the document on "setting up of a plant" the Secretariat indicated that it was completed with background notes according to the recommendations of the Ad-Hoc Panel, in particular concerning the presentation of the text and illustrative clauses.

29. After a brief discussion the Panel decided to concentrate on the first document dealing with "arrangements for the formulation of dosage forms".

30. An exchange of views took place in a plenary session with regard to the type of pharmaceutical formulations the document intended to cover. The Panel discussed the different aspects dealt with in the introduction and suggested the need for a number of changes and improvements. In order to consider them in detail, a small working group was established. The Panel thereafter considered the various comments and illustrative clauses relating to the recitals, definitions and technical information.

31. In view of the complexity of the topics and time constraints, the Panel agreed to set up two working-groups to discuss documents on "Formulations" and "Setting up of a Plant" respectively. At the end of the afternoon session the work done in each group was reported

to the Panel, and in the light of the progress reached, the Panel decided to continue working with the same procedure until each group could finalize the considerations of the respective documents.

32. The amendments and changes suggested by the participants will be reflected in the final draft of the documents to be presented at the Second Consultation.

33. Finally, the Panel agreed that before printing and translation of both documents, they should be reviewed by some members of the Panel. Thus, the following was agreed:

i) Mr. Stambouli from Tunisia and Mr. Peretz from the IFPMA would concentrate on the document concerning "Formulations";

ii) Ms. Roque-D'Oliveira from Portugal and Mr. Bago from Argentina would review the document on the "Seeting up of a Plant".

Final comments were received by UNIDO up to mid-June 1983 and which were included in the final documents.

D. Conclusions and recommendations

34. The Ad-hoc Panel, after agreeing with the three documents, recommended UNIDO that they be presented to the Second Consultation.

35. The Ad-Hoc Panel requested UNIDO to present at the Second Consultation if time and resources permit:

(a) The guidelines on patent law and its consequences for the producers of formulations and bulk drugs and for licensing agreements relating thereto;

(b) A survey of developing countries with regard to the type and extent of industrial protection relating to pharmaceutical product and process and export restrictions;

(c) A survey on the WHO Essential List of Drugs in order to examine whether patents (process and product) protection exists.

From the above only the report on (b) could be completed and, as requested, it is being presented to the Second Consultation.

36. The Ad-Hoc Panel recommended for the consideration of the Second Consultation that UNIDO prepare the following documents:

(a) A document with items which could be included in turnkey contractual arrangements for the setting up of a plant for the production of Bulk Drugs (or intermediates) included in the UNIDO Illustrative List;

(b) A document containing arrangements for technical assistance for the formulation of pharmaceutical forms.

III. PRESENTATION OF THE ISSUE TO THF SECOND CONSULTATION

37. The Ad-hoc Panel recommended that UNIDO present to the Second Consultation, within the issue of contractual arrangements, the following:

a) The three documents as agreed by the Panel.

b) The recommendation to undertake the preparation of the two additional documents mentioned in para.36 above.

c) The reference studies mentioned in para.35 that would have been completed if time and resources permitted.

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Second Meeting of the ad-hoc Panel of Experts on Contractual Arrangements in the Pharmaceutical Industry

ANNEXURE B

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