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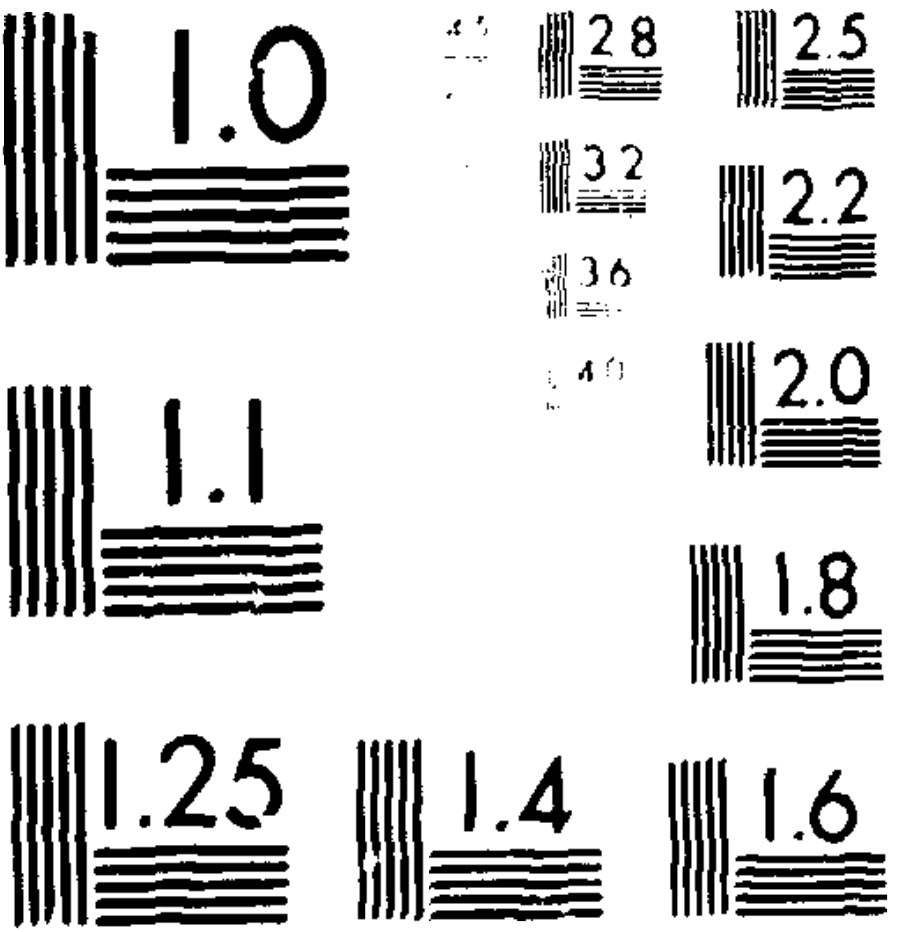

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Second Meeting of the Ad-Hoc Panel of Experts on Contractual Arrangements in the Pharmaceutical Industry.

Vienna, Austria 25-29 April, 1983

REPORT*/ (Contracting, pharmaceutical industry).

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ANNEXES

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", par.66.

2/ Official Records of the General Assembly, Seventh Special Session, Supplement No. 1, par. 3.

3/ The System of Consultation (P1/84)

4/ P1/84, par. 1.

5/ Ibid, par. 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 Estorial, Portugal, from 1 to 5 December, 1980. 8/ As a follow-up UNIDO convened a Round Table Meeting on the Pharmaceutical Industry in Mohammedia, Morocco, from 2 to 3 December, 1982. 9/ As recommended by the First Consultation the First Meeting of the Ad Hoc Panel of Experts was convened in Vienna from 15 to 17 December, 1982. 10/ This meeting recommended that a second meeting of the Ad Hoc Panel of Experts be convened from 25 to 29 April, 1983. The names of the participants are listed in Annex 1.

6/ Ibid, par. 23

7/ Ibid, par. 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.

10/ Report of the First Meeting of the Ad Hoc Panel ID/WG.385/4.

I. ORGANIZATION OF THE MEETING

Opening of the Meeting

1. The Meeting was opened by Mrs. A. Tcheknavorian-Asenbauer, Chairperson of UNIDO Task Force on Pharmaceutical, Chief-Pharmaceutical Industries Unit, UNIDO. She welcomed participants to the second meeting of the Ad Hoc Panel of Experts on Contractual Arrangements in the Pharmaceutical Industry.

2. Mrs. Tcheknavorian briefly recalled the mandate for this second meeting, referring to the recommendation of the First Consultation meeting of the Pharmaceutical Industry, and the Round Table meeting at Mohammedia, Morocco. Then, she went through the conclusions, and recommendations of the first meeting of the Ad Hoc panel and as recommended, highlighted the presence of new participants from developing countries, namely, a representative from the Andean group countries, Argentina, Cameroon and Tunisia.

3. Referring to the participants at the first meeting, Mrs. Tcheknavorian highlighted the fact that UNIDO had made every effort to secure the attendance of the same members at this second meeting. She also informed those present that as far as the preparation of a detailed study on - relevant issues to be taken into account when negotiating Transfer of Technology agreements - is concerned, UNIDO has already selected one of the experts suggested by the IFPMA, and a considerable amount of work has been carried out already. Should time permit, an informal presentation of this work may be made.

4. As far as case studies on transfer of technology agreed by the participants was concerned, Mrs. Tcheknavorian informed the participants that some elements had been received from certain countries. If possible, during the week the matter would be discussed further and in more detail.

5. Regarding documentation for the meeting, Mrs Tcheknavorian stated that the preparation of documents to be discussed by the panel was made on the lines of recommendations made at the first meeting, and informed the participants that this meeting would deal mainly with the documents which

considered "Items to be included in Licensing Agreements for the Transfer of Technology for the Formulation of Pharmaceutical Forms", and the "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 the UNIDO Illustrative List". The document dealing with the "Arrangements for the Production of Bulk Drugs" which was dealt with at the December 1982 meeting, has now been finalized, but UNIDO would welcome any final comments on this document. 11/

6. Finally, Mrs. Tcheknavorian referred to the constructive spirit prevalent at the December meeting, and hoped that the same spirit would continue during this second meeting.

Election of Officers

7. Mr. S. Ramanathan, India, Chairman of the First Ad Hoc Meeting was called upon again to chair this meeting, on the assumption that the work to be dealt with during the week was a continuation of that of the first meeting.

8. Mr. Ramanathan accepted with pleasure the task and expressed his thanks for the confidence of the participants in his direction of the meeting.

Documentation

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

Adoption of the Report

10. The report of the meeting was adopted on 29 April, 1983.

11/ ID/WG.393/1.

II. REPORT ON THE ISSUE - SUMMARY OF DISCUSSION

11. The Secretariat briefly submitted to the consideration of the Panel:

- 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) was revised taking into account the comments and recommendations made during the meeting of the Ad-Hoc Panel held from 15-17 December, 1982.

12. With regard to the document concerning "Licensing Arrangements" for the formulation of dosage forms, the Secretariat indicated that the revision included the following:

a) The introduction of the document was substantially reduced;

b) The scope of the paper was broadened in order to cover the situation where a new formulation unit is to be established, in addition to the hypothesis 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 above mentioned Ad-Hoc Panel were also considered wherever relevant.

13. In connection with the document on the "setting up of a plant" the Secretariat indicated that the document was completed with background notes, and that the general recommendations of the said Panel were also followed, particularly with regard to the presentation of the text and illustrative clauses.

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

15. 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 chapter titled '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.

16. In view of the complexity of the issues involved and the time constraints, the Panel agreed to set up two working-groups in order to deal respectively with the document on 'Formulations' and the document on 'Setting up of a Plant'. 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.

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

18. Finally, the Panel agreed that before the final printing and translation of the two 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'Oliviera from Portugal and Mr. Bago from Argentina would review the document on the "Setting up of a Plant".

Final comments would be forwarded to UNIDO by 10 June, 1983.

III. CONCLUSIONS AND RECOMMENDATIONS

1. 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;

2. 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 turn-key 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.

ANNEX I

LIST OF PARTICIPANTS

Andean Group

Luis Gustavo Florez
Jefe Departamento de Desarrollo Industrial
Junta del Acuerdo de Cartagena

Argentina

Sebastian Bagó
Vice-President
Laboratorios Bago S.A.

Cameroon

Geneviève Abondo
Chef de la Pharmacie Centrale du Cameroon

Egypt

Ahmed Ali Aboul-Enein
Chairman and Managing Director
Chemical Industries Development - Egypt

France

Daniel Biret
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Division Industries Pharmaceutiques

Germany, Federal Republic of

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Hoechst AG - Frankfurt

Hungary

Gyorgy Jancsó
Head of Department
Association of Hungarian Pharmaceutical Industries

India

V. Ramanathan
Secretary
Ministry of Chemicals and Fertilizers
Government of India

Portugal

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Foreign Investment Institute

Switzerland

Ernst Vischer
Deputy Chairman of the Board
Ciba-Geigy AG

Tunisia

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Pharmacie Centrale de Tunisie

United Kingdom

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Wellcome Foundation Ltd.

United States of America

Paul A. Belford
Director, International Issues Analysis
Pharmaceutical Manufacturers Associations

ORGANIZATIONS

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Executive Vice-President
I.F.P.M.A.

OBSERVERS

France

E. Barral

R. Tailhades

Portugal

Olimpia Cardoso

CONSULTANTS

Dr. L.K. Behl
Vishwakarma Process Technik Indis (p) Ltd.

Dr. Carlos Correa
Director
Gabinete de Investigaciones y Documentación

ANNEX II

LIST OF DOCUMENTS

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.	ID/WG.393/1	E
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 the Unido Illustrative list.		E/F/S
Items which could be Included in Licensing Arrangements for the Transfer of Technology for the Formulation of Pharmaceutical Dosage Forms.		E/F/S

BACKGROUND DOCUMENTS

Report of the First Consultation of the Pharmaceutical Industry, Lisbon, Portugal	ID/295	E/F/S
Report of the Round Table Meeting on the Development of the Pharmaceutical Industry, Mohammedia, Morocco.	UNIDO/PC.33	E/F