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

Vienna, Austria, 22-24 April 1985

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 Consultations (PI/84)

4/ PI/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 group 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 1-5 December 1980. 8/ The Consultation recommended the establishment of an adhoc panel of experts to examine Contractual Arrangements in the pharmaceutical industry. The panel of experts was thus established and held two meetings in Vienna from 15 to 17 December 1982 9/ and 25 to 29 April 1983, 10/ respectively. The Second Consultation on the Pharmaceutical Industry was convened in Budapest, Hungary, from 21-25 November 1983 11/ and discussed, inter-alia, the work prepared by the Secretariat in co-operation with the adhoc panel of experts on contractual arrangements. As recommended by the Second Consultation, the Third Meeting of the Ad-hoc Panel of Experts was convened from 22-24 April 1985 in Vienna and finalized the three documents on contractual arrangements mentioned in paragraph 1 of this report. The names of the participants at the last panel meeting are listed in Annex I.

6/ Ibid, para. 22.

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, PC33, 21 January 1982

10/ Report of the First and Second Meeting of the Ad-hoc Panel of Experts on Contractual Arrangements in the Pharmaceutical Industry. ID/WG.385/4 and UNIDO/PC.62, 18 January 1983 and 18 May 1983, respectively.

11/ Report of the Second Consultation on the Pharmaceutical Industry, ID/311

I. ORGANIZATION OF THE MEETING

Opening of the Meeting

1. The Third Meeting of the Ad-hoc Panel on Contractual Arrangements was opened by the Chairperson of UNIDO Interdivisional Task Force on the Pharmaceutical Industry and Acting Head of Chemical Industries Branch who welcomed the participants. The Secretariat highlighted the fact that UNIDO had made every effort to secure the attendance of the same members as for the earlier meetings in order to assure continuity of work. The names of the participants who attended the meeting are given in Annex I.

2. The Secretariat briefly recalled the mandate for this meeting with regard to the contractual arrangements for the production of pharmaceuticals, referring to the recommendations of the Second Consultation on the Pharmaceutical Industry. It included finalization of three documents (ID/WG.393/1, 3, 4) discussed at the consultation, and arrangements for their dissemination, discussion on outlines for three new documents and preparation of these documents for discussion by the Panel as well as the preparation of a reference paper on areas not covered in the three documents mentioned above.

3. Regarding documentation for the meeting, it was stated that the working papers have been prepared by the Secretariat taking into account the comments and statements made at the Second Consultation aiming at finalization of three documents, namely:

- 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, 26 May 1983).
- Items which could be included in licensing arrangements for the transfer of technology for the formulation of pharmaceutical dosage forms (ID/WG.393/3, 9 July 1983).
- 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 (ID/WG.393/4, 14 July 1983).

4. The Secretariat informed that the finalized version of the documents would be widely disseminated by UNIDO. Besides this, a paper entailing some of the relevant issues not covered in the above referred documents would be discussed by the Panel.

5. The Panel would also be requested to consider and review the outlines prepared by the Secretariat for the preparation of new documents on:

- Items which could be included in contractual arrangements for the setting up of a turn-key plant for the formulation of pharmaceutical forms
- Items which could be included in contractual arrangements for the setting up of a turn-key plant for the production of bulk drugs (or intermediates) included in UNIDO list
- Items which could be included in contractual arrangements for technical assistance for the formulation of pharmaceutical forms

6. The UNIDO secretariat would prepare the draft of these three documents which would then be reviewed, discussed and finalized by the Fourth Meeting of the Ad-hoc Panel for submission to the Third Consultation.

7. The Secretariat briefly explained the participants various administrative arrangements.

Election of Officers

8. Mr. S. Ramanathan, Chairman of First and Second Ad-hoc Panel Meeting, and Mr. E. Vischer, Chairman of Working Group I at the Second Consultation, were elected as Chairman and Co-chairman respectively.

Documentation

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

II. CONCLUSIONS AND RECOMMENDATIONS

10. The Third Ad-hoc Panel on Contractual Arrangements in the Pharmaceutical Industry discussed the following documents presented by the UNIDO Secretariat:

a. 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, 26 May 1983)

b. Items which could be included in licensing arrangements for the transfer of technology for the formulation of pharmaceutical dosage forms (ID/WG.393/3, 9 July 1983)

c. 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 (ID/WG.393/4, 14 July 1983)

Taking into consideration the various comments and statements made at the Second Consultation meeting, the panel finalized the documents referred to above and requested UNIDO to report accordingly to the Third Consultation on the Pharmaceutical Industry.

11. The panel recommended that UNIDO secretariat should review the annexes attached to the above-mentioned documents with the object of their improvement, updating and completion.

12. The panel recommended wide dissemination of these documents at an early date to interested parties in developing and developed countries.

13. It further recommended that UNIDO taking into consideration the comments it receives on these documents as to their usefulness, should determine the need for their further updating with the assistance of the panel.

14. The panel also discussed the outlines of three additional documents, namely:

- Items which could be included in contractual arrangements for the setting up of a turn-key plant for the formulation of pharmaceutical forms

- Items which could be included in contractual arrangements for the setting up of a turn-key plant for the production of bulk drugs (or intermediates) included in UNIDO list

- Items which could be included in contractual arrangements for technical assistance for the formulation of pharmaceutical forms

and recommended UNIDO to prepare the required documents based on the above referred outlines.

15. The draft reference paper, namely "Areas not covered in documents no. ID/WG.393/1, 393/3 and 393/4" was discussed. UNIDO was recommended to complete this paper.

16. It was recommended to convene a Fourth Meeting of the Ad-hoc Panel from 10-14 March 1986 in order to discuss clause by clause and finalize the documents referred to in paras 14 and 15. The documents should then be submitted to the Third Consultation on the Pharmaceutical Industry.

III. SUMMARY OF THE DISCUSSIONS

17. The Secretariat briefly presented the revised documents on

- 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, 26 May 1983)
- Items which could be included in licensing arrangements for the transfer of technology for the formulation of pharmaceutical dosage forms (ID/WG.393/3, 9 July 1983)
- 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 (ID/WG.393/4, 14 July 1983)

for the consideration of the Panel. The revised clauses for each of the documents were discussed. The suggested changes and amendments as agreed upon by the Panel were incorporated in the text of the main documents. The Panel finalized these documents.

18. It was emphasized that the documents required improvements by way of editing of English version and correction in the French text. It was also agreed that the Annexes to the documents be rechecked.

19. The documents nos. ID/WG.393/1, 3, 4 would be widely disseminated after their finalization by the Secretariat taking into account the discussion and conclusions of the Panel.

20. It was emphasized that these documents would be of immense benefit to the intending users in the developing countries and would furthermore assist in North-South and South-South dialogue on international cooperation for the development of the pharmaceutical industry. In addition, these documents would be greatly used for the enhancement of technical cooperation among developing countries.

21. The outlines for documents on:

- Items which could be included in contractual arrangements for the setting up of a turn-key plant for the formulation of pharmaceutical forms,

- Items which could be included in contractual arrangements for the setting up of a turn-key plant for the production of bulk drugs (or intermediates) included in UNIDO list, and

- Items which could be included in contractual arrangements for technical assistance for the formulation of pharmaceutical forms,

were discussed and agreed upon in principle. However, concern was expressed by participants with regard to insufficient time for the preparatory work. It was also agreed to highlight the positive as well as negative aspects (advantages/disadvantages) in the preamble of the turnkey contracts, in particular for those who are establishing a pharmaceutical industry for the first time. In the case of the contract for technical assistance, it was proposed to add chapters on technology, language/terminology, selection of training, engineering services, start up, commissioning, availability of experts at site, penalties and subcontracting etc.

22. The participants agreed to advise the Secretariat by written comments on the supplementary document related to areas not covered in documents ID/WG.393/1, 393/3 and 393/4 mentioned in paragraph 15 by 18 June 1985.

23. It was suggested that UNIDO should tackle the issue of development of competent management in developing countries and take steps for practical activities for its promotion such as exchange of experiences, etc. The Secretariat advised that the suggestion is appreciated and that UNIDO is already considering the issues of "Planning and Management" and "Exchange of Experiences" for implementation. It was further said that an action oriented draft paper on the issue would be prepared for discussion and advice at the Fourth Meeting of the Panel in March 1986 and then submitted for consideration at the Third Consultation.

24. The Secretariat thanked the members of the Panel on behalf of the Executive Director of UNIDO and Head of Negotiations Branch for their assistance to UNIDO. Mr. Bernek expressed thanks to the Secretariat and the Chairman on behalf of all participants for the co-operation and fairness in dealing and assisting the Panel in accomplishing the task assigned to it by the Second Consultation.

ANNEX I

LIST OF PARTICIPANTS

Brazil	Mr. Alberto Mansur Head of Development Department NORQUISA
Egypt	Dr. Ahmed A. Aboul-Enein Pharmaceutical Consultant for Ministry of Health
France	Mr. Daniel Biret Ministere de l'Industrie
Germany, Federal Republic of	Dr. Karl F. Gross Director Hoechst AG
Hungary	Prof.Dr. György Fekete Assistant General Manager Chemical Works of Gedeon Richter Ltd.
India	Mr. S. Ramanathan Secretary (Coordination) Cabinet Secretariat
Philippines	Mrs. Catalina C. Sanchez Director Bureau of Food and Drugs Ministry of Health
Spain	Mr. Antonio F. Cano-Martin Ministerio de Industria y Energia Jefe Servicio Calidad Industrial y Tecnologia
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USA	Mr. Joseph M. Bernik Vice President Abbott International Ltd.

ORGANIZATIONS	Mr. Richard B. Arnold Executive Vice President IFPMA	
OBSERVERS	Brazil	Mr. Isaac Gabai Development Assistant NORQUISA
	France	Mr. Etienne Barral Rhone Poulenc Sante
		Mr. Henri Desarmenien Conseiller
CONSULTANTS	Mr. Carlos M. Correa Florida, Argentina	

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 ID/WG.393/1/Add.1 26 May 1983	E/F/S E
Items which could be included in licensing arrangements for the transfer of technology for the formulation of pharmaceutical dosage forms	ID/WG.393/3/Add.1 ID/WG.393/3 9 July 1983	E E/F/S
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	ID/WG.393/4/Add.1 ID/WG.393/4 14 July 1983	E E/F/S
Report of the Second Consultation on the Pharmaceutical Industry, Budapest, Hungary	ID/311 21-25 November 1983	E

Outlines

- Items which could be included in contractual arrangements for technical assistance for the formulation of pharmaceutical forms	E
- Items which could be included in contractual arrangements for the setting up of a turn-key plant for the formulation of pharmaceutical forms	E
- Items which could be included in contractual arrangements for the setting up of a turn-key plant for the production of bulk drugs (or intermediates) included in UNIDO list	E
- Reference paper - Areas not covered by documents ID/WG.393/1, 3 and 4	E