OCCASION

This publication has been made available to the public on the occasion of the 50th anniversary of the United Nations Industrial Development Organisation.

DISCLAIMER

FAIR USE POLICY

CONTACT

Please contact publications@unido.org for further information concerning UNIDO publications.

For more information about UNIDO, please visit us at www.unido.org

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

17092-E

Distr.
LIMITED

ID/WG.466/9(SPEC.)
22 April 1987

ENGLISH

United Nations Industrial Development Organization

Third Consultation on the
Pharmaceutical Industry

Madrid, Spain, 5-9 October 1987

REVIEW OF WORK ON CONTRACTUAL ARRANGEMENTS FOR THE PRODUCTION OF PHARMACEUTICAL CHEMICALS, THEIR INTERMEDIATES AND FORMULATIONS *

Prepared by

the UNIDO Secretariat

* This document has been reproduced without formal editing.

V.87-84420

CONTENTS

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 a 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.

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.

6. The documents referred to in para. 4 were discussed at the Second Consultation on the Pharmaceutical Industry. Thereafter, these were finalized by the Ad-hoc Panel of Experts in April 1985, taking into account the comments and suggestions made at the Second Consultation. The documents have since been disseminated widely.

7. In accordance with the recommendations of the Second Consultation, additional documents on this issue have been prepared by the Secretariat for presentation at the Third Consultation.

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

8. The Round Table Meeting was convened at Mohammedia, Morocco, from 2 to 3 December 1981 on the develop ent of the pharmaceutical industry. The meeting advised UNIDO on the actions to be taken to implement the recommendations of the First Consultation. It was attended by 22 participants from 15 countries and the industry. The conclusions and recommendations of the meeting on the subject of contractual arrangements were the following: *

9. 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;

---

* For detail see report UNIDO/PC.33

d) duly consider the main factors that hamper the successful transfer of technology and the development of the pharmaceutical industry in developing countries.

10. 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.

11. 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.

12. Among other items to be included 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.

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

II. MEETINGS OF THE ADHOC 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 1983. The list of the Ad-hoc Panel members is given in Annexures of the reports. *

III. CONCLUSIONS AND RECOMMENDATIONS OF THE SECOND CONSULTATION ON THE ISSUE:

15. The Consultation took note of the three documents on contractual arrangements (ID/WG.393/1, 3 and 4) worked on by the members of the Ad-hoc Panel of Experts. These documents received the complete support of the developing countries. Although the Consultation considered those documents to be of great value, it however, was unable to reach full agreement on them because of differences of opinion on certain points of those documents between developed and developing countries.

16. The Consultation recommended that:

(a) UNIDO should reconvene the Ad-hoc Panel at an early date in order to finalize the three documents in the light of comments and suggestions made at the Consultation;

(b) UNIDO should disseminate the completed documents as widely as possible to interested parties in developing and developed countries acknowledging that they were finalized by the Ad-hoc Panel;

(c) UNIDO should assess, with the assistance of the Ad-hoc Panel, the usefulness of the documents two to three years after their dissemination in order to determine the need for their revision;

(d) UNIDO, in co-operation with the Ad-hoc Panel, should identify areas not covered by the three documents and prepare a reference paper covering those areas. This paper should be distributed immediately to interested parties in developing and developed countries. The Ad-hoc Panel may recommend that UNIDO submit the reference paper in an appropriate form to the Third Consultation;

(e) UNIDO, in co-operation with the Ad-hoc Panel, should prepare documents on:

  (i) Items that could be included in contractual arrangements for the setting up of turn-key plants for the production of bulk drugs or intermediates, included in the UNIDO illustrative list and for the production of formulations;

  (ii) Arrangements for technical assistance for the formulation of pharmaceutical forms.

17. Those documents should be submitted to the Third Consultation.

---

* For details see Reports ID/WG.385/4 and UNIDO/PC.62

IV. THIRD MEETING OF THE ADHOC PANEL OF EXPERTS ON CONTRACTUAL ARRANGEMENTS

18. The Third Meeting of the Ad-hoc Panel was convened from 22 to 24 April 1985 in Vienna.

19. The Panel finalized the three documents on contractual arrangements listed hereunder taking into account the comments and suggestions made at the Second Consultation:

- 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/Rev.2),

- Items which could be included in licensing arrangements for the transfer of technology for the formulation of pharmaceutical dosage forms (ID/WG.393/3/Rev.2),

- 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/Rev.2).

20. The Meeting also reviewed the draft reference paper on the "Areas not covered in documents no. ID/WG.393/1, 3 and 4".

21. The Panel discussed the outlines for the new documents to be prepared on

- 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 the setting up of a turn-key plant for the formulation of pharmaceutical forms

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

V. STATUS OF COMPLETED DOCUMENTS

22. The completed documents mentioned in para. 19 have been widely disseminated by UNIDO to interested parties in developing and developed countries. In few years time and on the basis of adequate response from users in developed and developing countries, UNIDO may with the assistance of Adhoc Panel would assess the usefulness of the documents already disseminated in order to determine the need for their revision.

VI. FOURTH MEETING OF THE ADHOC PANEL

23. No additional Panel meeting could be convened due to budgetary constraints by UNIDO. However, the four documents mentioned in paragraphs 20 and 21 above have been finalized by the Secretariat taking into account the written comments of the members of the Panel.

VII. PRESENTATION TO THE THIRD CONSULTATION

24. According to the recommendations of the Second Consultation, UNIDO presents to the Third Consultation the underlisted documents.

(A) The reference paper on "Areas not covered in documents ID/WG.393/1, 3 and 4" mentioned in paras. 16(d) and 20.

This document deals with additional clauses, the inclusion of which would complete the existing three documents no. ID/393/1, 3 and 4, the first two on licensing arrangements for transfer of technology for the manufacture of pharmaceutical chemicals, their intermediates and for the production of formulation of pharmaceutical dosage forms, and the third on setting up of plants for the production of pharmaceutical chemicals respectively.

The texts should be inserted into the existing finalized documents, i.e. ID/WG.393/1/Rev.2, ID/WG.393/3/Rev.2 and ID/WG.393/4/Rev.2.

(B) The three documents relating to turnkey and technical assistance arrangements as mentioned in para. 21.

(i) Items which could be included in contractual arrangements for the setting up of a turnkey plant for the production of bulk drugs (pharmaceutical chemicals and their intermediates)

This document provides general guidelines and proposals to be applied in negotiating the setting up of turnkey plants for the production of pharmaceutical chemicals and their intermediates included in the UNIDO illustrative list. The document primarily deals with "cost reimbursable" type of contracts, whereunder the contractor is remunerated by a firm price, plus a variable price determined on the basis of the cost incurred for provision of management assistance and supervisory services for erection, commissioning and start up of the plant as well as for other activities set forth in the contract. The document is mainly addressed to enterprises in developing countries which are able and willing to set up domestic production facilities for pharmaceutical chemicals and/or their intermediates.

(ii) Items which could be included in contractual arrangements for the setting up of a turnkey plant for the production of pharmaceutical dosage forms

This document provides general guidelines, and proposals to be applied in negotiating the setting up of turnkey plants for the production of pharmaceutical formulations. The document is based on the "lump sum" type of turnkey agreement. The modality prevails where the recipient lacks previous experience and knowledge in the field. The document is mainly addressed to enterprises in developing countries.

(iii) Items which could be included in the contractual arrangements for technical assistance for the formulation of pharmaceutical dosage forms

This document provides general guidelines and proposals to be applied in negotiating the arrangement for technical assistance for the production of

pharmaceutical dosage forms. The document is intended to provide guidance for the negotiation and drafting of contracts for new entrepreneurs or those who have already a plant in operation and would like to add new products or adopt new technology.

All three documents include, when appropriate:

(i) Elements to be taken into account in the negotiation and drafting of the clauses;

(ii) Technical aspects, and particularly difficulties that may be faced at the negotiating phase and implementation of the agreement;

(iii) Concrete examples, wherever possible;

(iv) Recommendations as how to deal with the particular issues;

(v) Possible clauses and variations thereof.

The illustrative clauses provided in the documents are presented as examples that could be used to achieve the purpose of the agreements; these clauses, however, should not be considered as being exhaustive on covering all possible situations that can arise in transfer of technology, contractual arrangements for setting up turnkey plants or technical assistance.

25. The material contained in the two documents on turnkey arrangements and one on technical assistance arrangements is the first attempt to provide negotiating parties with a practical instrument adapted to the requirements of the sector at hand and to the specific needs of enterprises in developing countries.

26. The originality and value of these documents as instruments for negotiation is due to the fact that they represent in themselves the product of a negotiation and concensus between representatives from developed and developing countries, incorporating thus experience and up-to-date knowledge of contractual arrangements in the pharmaceutical industry.

27. Participants at the Third Consultation are thus invited to take note of action taken by the Secretariat and to make use of these documents in negotiating contracts for the establishment of plants and/or transfer of pharmaceutical technologies.

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

ANNEXURE A

LIST OF PARTICIPANTS

CHINA	Zheng Chi Deputy Director Shanghai Pharmaceutical Design Institute
EGYPT	Ahmed Ali Aboul Enein Chairman Chemical Industries
FRANCE	Daniel Biret Sous - Directeur au Ministere de la Recherche et de l'Industrie Direction des Industries Chimiques, Textiles et Diverses Division Industries Pharmaceutiques
HUNGARY	Gyorgy Jancso Association of Hungarian Pharmaceutical Industries
INDIA	S. Ramanathan Secretary Department of Chemicals and Fertilizers Government of India
GERMANY Federal Republic of	Dr. Karl F. Gross Director Hoechst AG - Frankfurt
MEXICO	Fermin Fernandez-Viana Coordinator General Industria Farmaceutica
PORTUGAL	Mrs. Isabel Roque D'Oliveira Member of the Board of Directors of the Foreign Investment Institute
SWITZERLAND	Dr. R. Vischer Vice-President Ciba-Geigy AG
UNITED KINGDOM	Dr. A. Worlock Group Marketing Director Wellcome Foundation Ltd.
UNITED STATES OF AMERICA	Paul A. Belford Pharmaceutical Manufacturers Association

ORGANIZATIONS	S.M. Peretz Executive Vice-President I.F.P.M.A.
OBSERVERS	Portugal Mrs. Olimpia Cardoso

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

ANNEXURE B

LIST OF PARTICIPANTS

ANDEAN GROUP	Luis Gustavo Florez Jefe Departamento de Desarrollo Industrial Junta del Acuerdo de Cartagena
ARGENTINA	Sebastian Bago Vice-President Laboratorios Bago S.A.
CAMEROON	Genevieve Abondo Chef de la Pharmacie Centrale du Cameroon
EGYPT	Ahmed Ali Aboul-Enein Chairman and Managing Director Chemical Industries Development
FRANCE	Daniel Biret Ministere de l'Industrie et de la Recherche Direction des Industries Chimiques, Textiles et Diverses Division Industries Pharmaceutiques
GERMANY Federal Republic of	Dr. Karl F. Gross Director Hoechst AG - Frankfurt
HUNGARY	Gyorgy Jancso Head of Department Association of Hungarian Pharmaceutical Industries
INDIA	S. Ramanathan Secretary Ministry of Chemicals and Fertilizers Government of India
PORTUGAL	Isabel Roque D'Oliveira Director Foreign Investment Institute
SWITZERLAND	Ernst Vischer Deputy Chairman of the Board Ciba-Geigy AG

TUNISIA	Ali-ben Mohamed Stambouli Directeur General Pharmacie Centrale de Tunisie	
UNITED KINGDOM	Dr. Arnold Worlock Director Wellcome Foundation Ltd.	
UNITED STATES OF AMERICA	Paul A. Belford Director, International Issues Analysis Pharmaceutical Manufacturers Associations	
ORGANIZATIONS	S.M. Peretz Executive Vice-President I.F.P.M.A.	
OBSERVERS	France	E. Barral R. Tailhades
	Portugal	Olimpia Cardoso

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

ANNEXURE C

LIST OF PARTICIPANTS

BRAZIL	Alberto Mansur Chief Development Adviser NORQUISA
EGYPT	Dr. Ahmed Aboul Enein Chemical Industries Development
FRANCE	Daniel Biret Ministere de l'Industrie et de la Recherche
GERMANY Federal Republic of	Dr. Karl F. Gross Senior Manager Hoechst AG
HUNGARY	Prof. Dr. Gyorgy Fekete Assistant General Manager Chemical Works of Gedeon Richter Ltd.
INDIA	S. Ramanathan Secretary Cabinet Secretariat

PHILIPPINES	Catalina Sanchez Director Bureau of Food and Drugs
SWITZERLAND	Dr. E. Vischer Vice-Chairman of the Board Ciba-Geigy
SPAIN	Antonio-Felipe Cano Martin Ministerio de Industria y Energia
TUNISIA	Dr. Ali Stambouli President de la Pharmacie Centrale
UNITED STATES	Joseph Bernik Vice President Abbott International, Ltd.
ORGANIZATIONS	Richard B. Arnold Vice-President I.F.P.M.A.