



TOGETHER
for a sustainable future

OCCASION

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



TOGETHER
for a sustainable future

DISCLAIMER

This document has been produced without formal United Nations editing. The designations employed and the presentation of the material in this document do not imply the expression of any opinion whatsoever on the part of the Secretariat of the United Nations Industrial Development Organization (UNIDO) concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries, or its economic system or degree of development. Designations such as “developed”, “industrialized” and “developing” are intended for statistical convenience and do not necessarily express a judgment about the stage reached by a particular country or area in the development process. Mention of firm names or commercial products does not constitute an endorsement by UNIDO.

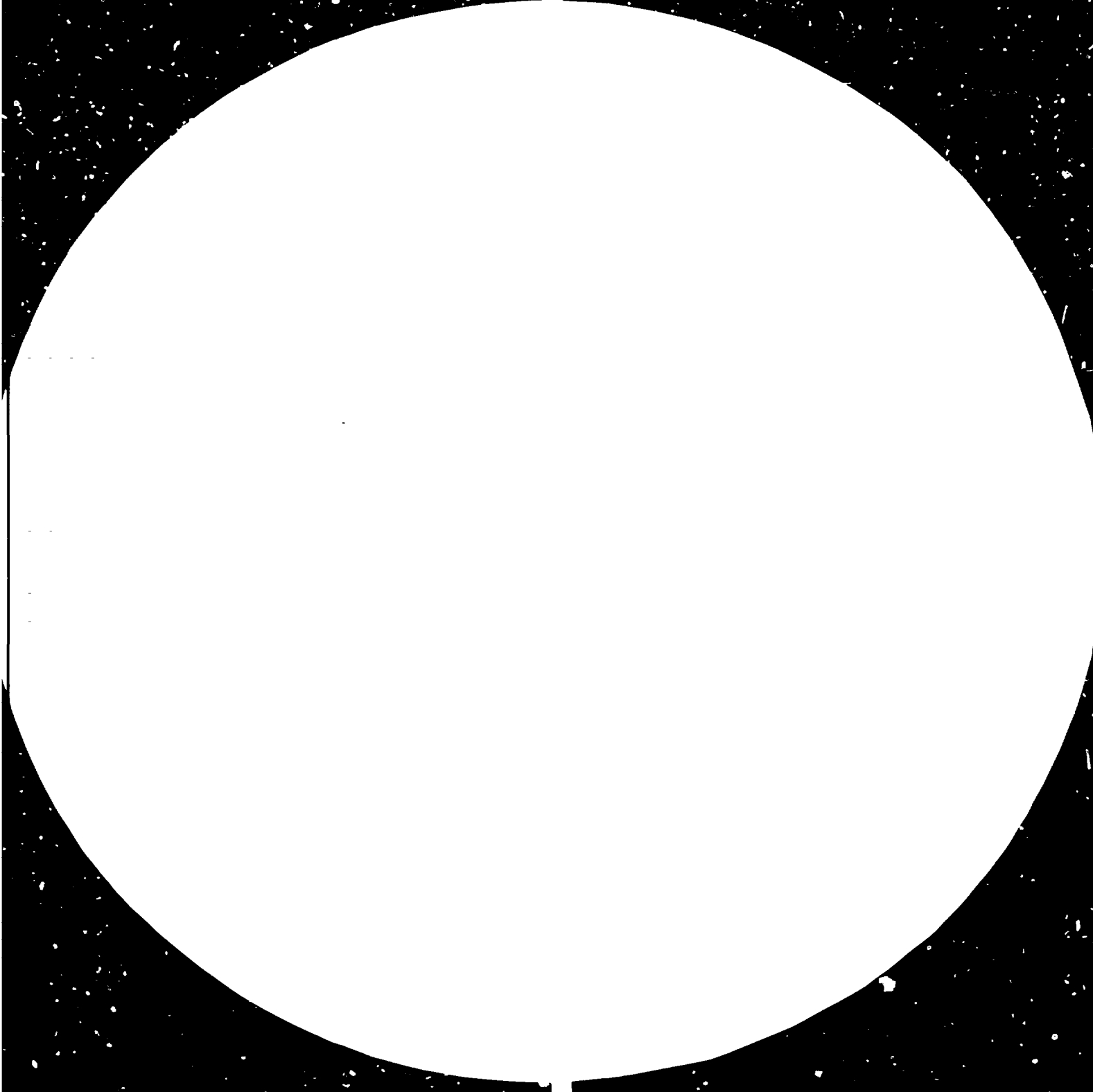
FAIR USE POLICY

Any part of this publication may be quoted and referenced for educational and research purposes without additional permission from UNIDO. However, those who make use of quoting and referencing this publication are requested to follow the Fair Use Policy of giving due credit to UNIDO.

CONTACT

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

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



10156



UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

**FIRST
CONSULTATION
ON THE
PHARMACEUTICAL
INDUSTRY**

Lisbon, Portugal, 1-5 December 1980

REPORT

001005

Distr.
LIMITED
ID/259
(ID/WG.331/10/Rev.1)
ENGLISH

Explanatory notes

UNCTAD United Nations Conference on Trade and Development
WIPO World Intellectual Property Organization



with
10156



Distr.
LIMITED

ID/259/Corr.1
(ID/WG.331/10/Rev.1/Corr.)

ORIGINAL: ENGLISH

United Nations Industrial Development Organization

FIRST CONSULTATION ON THE
PHARMACEUTICAL INDUSTRY

Lisbon, Portugal, 1-5 December 1980

REPORT

Corrigendum

Page 7, line 9

For of read for

Page 18

Lines 4, 5 and 6 should read

UNCTAD intergovernmental negotiating conference and a UNIDO Consultation, a representative stressed that while UNCTAD could draw up a framework text concerning the code of conduct on the transfer of technology, UNIDO, meeting at a Consultation

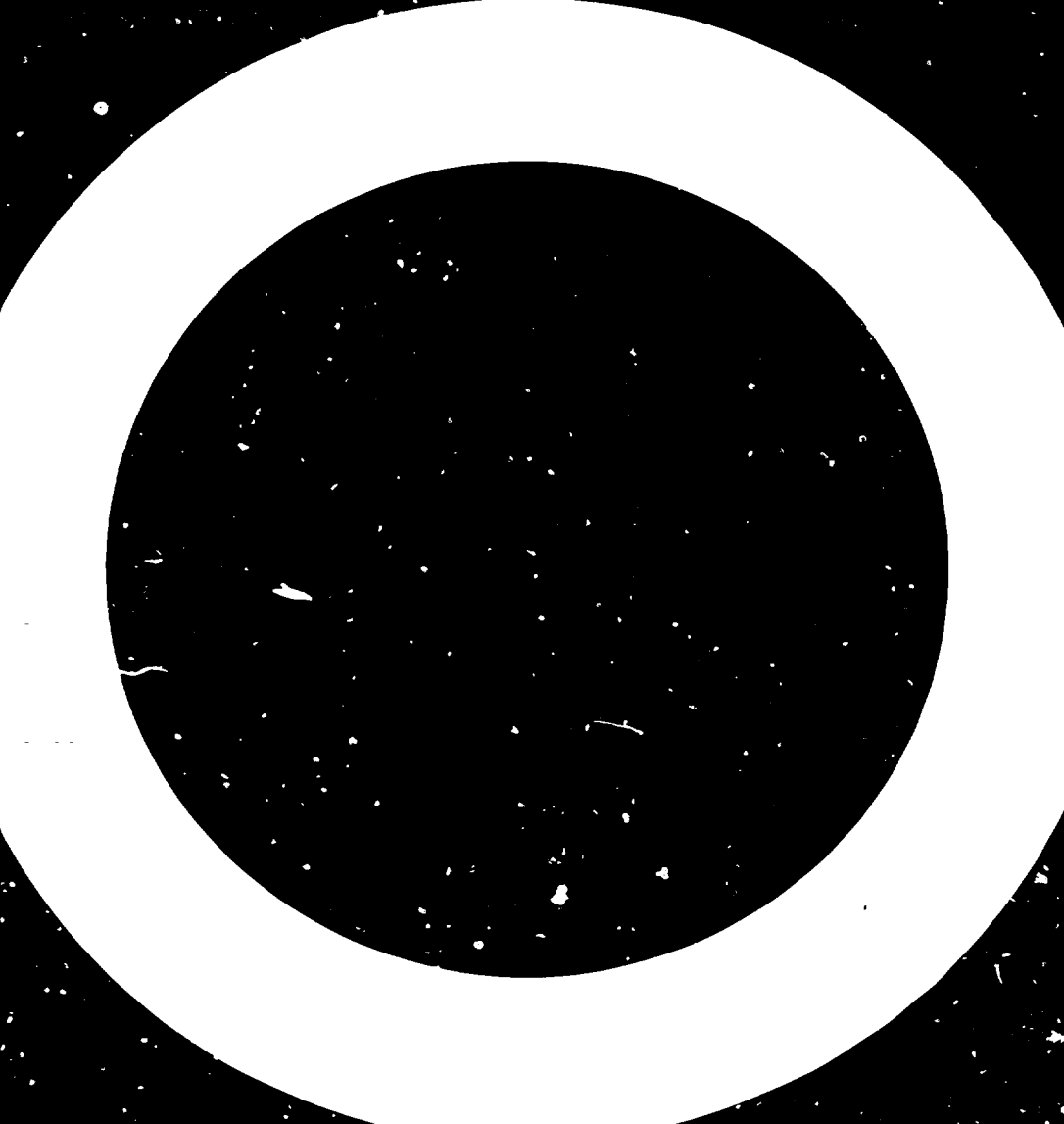
Page 22

Line 3 should read

Participants from a few countries gave written preliminary information concerning the drugs

Page 27, line 2

The name should read Cadangode Venkateswara Subra Mani



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 negotiation 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. The Board, at its thirteenth session in 1979, decided that the First Consultation on the Pharmaceutical Industry should be held during 1980.^{3/} At its fourteenth session, the Board decided to establish the System of Consultations on a permanent basis with the following main characteristics, including those described in its past decisions:

(a) The System of Consultations should be an instrument through which the United Nations Industrial Development Organization (UNIDO) would serve as a forum for developed and developing countries in their contacts and consultations directed towards the industrialization of developing countries; ^{4/}

^{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/} Official Records of the General Assembly, Thirty-fourth Session, Supplement No. 16.

^{4/} Ibid., Thirty-fifth Session, Supplement No. 16, para. 151(a).

(b) Consultations would also permit negotiations among interested parties at their request, at the same time as or after Consultations; 5/

(c) 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/

(d) Final reports of the Consultations should include such conclusions and recommendations as agreed upon by consensus by the participants as well as other significant views expressed during the discussion. 7/

Draft rules of procedure for the System of Consultations are to be submitted for consideration and adoption by the Board at its fifteenth session in 1981.

5/ Ibid., para. 151(b).

6/ Ibid., para. 152.

7/ Ibid., Thirty-second Session, Supplement No. 16, para. 163.

CONTENTS

<u>Chapter</u>	<u>Page</u>	<u>Paragraph</u>
INTRODUCTION.....	6	
CONCLUSIONS AND RECOMMENDATIONS.....	6	1-7
I. ORGANIZATION OF THE CONSULTATION.....	9	8-14
II. THE GLOBAL STUDY ON THE PHARMACEUTICAL INDUSTRY.....	11	15-27
III. ISSUES RECOMMENDED BY THE GLOBAL PREPARATORY MEETING		
Issue 1. The pricing and availability of intermediates and bulk drugs.....	14	28-35
Issue 2. Contractual arrangements for the production of drugs.....	15	36-73
Issue 3. The availability, terms and conditions for the transfer of technology for the manufac- ture of essential drugs included in the illustrative list prepared by UNIDO in consultation with WHO.....	21	74-80

Annexes

I. List of participants.....	23
II. List of documents.....	36

INTRODUCTION

The First Consultation on the Pharmaceutical Industry was held at the Hotel Estoril-Sol, Estoril, Portugal, from 1 to 5 December 1980. The Consultation was attended by 217 participants (annex I) representing Governments, industry, labour and consumer groups from 68 countries and 13 international organizations.

CONCLUSIONS AND RECOMMENDATIONS

1. In connection with the discussion on Issue 1, the First Consultation recommended the setting-up of a UNIDO Committee of Experts on Pharmaceuticals composed of members from developing and developed countries, under the auspices of UNIDO, to discuss the technical and economic aspects of the availability of intermediates and bulk drugs:

(a) The Committee will be dedicated to the concept of and committed to highlighting the need for evolving a better understanding of matters relating to the availability of those bulk drugs (and the necessary intermediates) included in the UNIDO illustrative list of 26 essential drugs, and to assisting developing countries in the production of these intermediate and bulk drugs;

(b) The members of the Committee, which would be a reasonable and small number, would be experts with professional experience selected by the UNIDO secretariat giving preference to the maximum possible extent to experts having participated in the First Consultation and representing all geographical groups, including countries with a major pharmaceutical industry;

(c) The Committee will complete its work in due time for the Second Consultation on the Pharmaceutical Industry.

2. In view of the discussions held on Issue 2, and the substantial differences expressed as to the content of items which could be incorporated into various contractual arrangements between parties interested in transfer of technology in the pharmaceutical industry, the First Consultation recommends that the UNIDO secretariat, in co-operation with an ad hoc panel of experts, selected on the basis of equitable geographical distribution, prepare a document, complete with the necessary background notes, on various terms, conditions and variations thereof that could be included in contractual agreements.

3. In addition, the UNIDO secretariat should undertake a detailed study on relevant issues to be taken into account when negotiating transfer of technology agreements as put forward in documents ID/WG.331/2 and Add.1, taking into account the experience of developed countries.

4. After considering Issue 3, the Consultation arrived at the following conclusions:

(a) The 26 essential drugs identified by UNIDO and essential and well defined products based on medicinal plants constitute an illustrative list of undertaking basic manufacture in developing countries;

(b) The developing countries as a group constitute large markets for these drugs where in certain cases the patents have lapsed;

(c) There is a willingness expressed by developed countries, centrally planned economies and transnational corporations to enable the transfer of technology to developing countries, bearing in mind the human health needs aspect of such transfers of technology;

(d) Transfers of technology have to take place on mutually acceptable and equitable terms;

(e) Manufacture to be based on maximum feasible backward integration to raw materials.

5. Such mutually acceptable transfers of technology should be facilitated through UNIDO providing reference information relevant to the transfer of technology, including technical aspects such as the level of production, magnitude of investments, inputs, infrastructure etc. which could be a significant aid to individual developing countries in bilateral negotiations for transfer of technology. The result of such transfers and experience should be brought to the attention of the Second Consultation on the Pharmaceutical Industry.

6. Furthermore it was agreed that technical co-operation among developing countries could play an effective role in the development of the pharmaceutical industry in developing countries especially in respect of the following:

(a) Emphasizing the need to develop local research and development to absorb, assimilate and further develop the technology acquired;

(b) Training;

(c) Quality control;

- (d) Exchange of information and experience;
- (e) Trade in raw materials and finished products.

7. It is recognized that the transfer of technology for drugs referred to in para. 4(a) above should be acceptable to the recipients and the suppliers of technology. It is suggested that serious consideration be given to joint ventures, licences and other commercial arrangements, with a view to UNIDO assisting developing countries in improving their negotiating positions through its reference and information resources in order to overcome impediments and to facilitate imports and exports and with a view to increasing trade in raw materials, intermediates, bulk drugs, equipment, and finished goods, and to increasing the transfer of technology to developing countries.

I. ORGANIZATION OF THE CONSULTATION

Opening of the meeting

8. The First Consultation on the Pharmaceutical Industry was opened by Eng. Alvaro Barreto, Minister of Industry and Energy of the Government of Portugal. The Consultation was then addressed by the Deputy Executive Director of UNIDO, on behalf of the Executive Director, who thanked the Government of Portugal for hosting the Consultation.

Election of officers

9. João Antunes Bartolo, General Director of the Chemical and Metallurgical Industries, Ministry of Industry (Portugal) was elected Chairman of the Consultation.

The following were elected as Vice-Chairmen:

Ahmed Aboul-Enein, Chairman and Managing Director, Chemical Industries Development (Egypt)

Lajos Csurgai, Deputy Minister, Ministry of Heavy Industry (Hungary)

C.V.S. Mani, Additional Secretary, Ministry of Health (India)

Enrique del Val-Blanco, General Director, Federal Procurement (Mexico).

Adoption of the agenda

10. The Consultation adopted the following agenda:

1. Opening of the Consultation and election of Chairman and Vice-Chairmen

2. Adoption of the agenda

3. Global Study on the Pharmaceutical Industry

4. Issues recommended by the Global Preparatory Meeting:

Issue 1 The pricing and availability of intermediates and bulk drugs

Issue 2 Contractual arrangements for the production of drugs:

Part 1 Relevant issues to be taken into account when negotiating a transfer of technology agreement

Part 2 Preparation of guidelines

Issue 3 The availability, terms and conditions for the transfer of technology for the manufacture of essential drugs included in the illustrative list prepared by UNIDO in consultation with WHO

5. Adoption of the report of the Consultation

Establishment of working groups

11. The Consultation decided that Issue 1 should be discussed in the plenary. Issues 2 and 3 included under agenda item 4 would be discussed in two open-ended working groups; one, on contractual arrangements for the production of drugs presided over by E. Vischer (Switzerland), and the other, on the availability, terms and conditions for the transfer of technology for the manufacture of essential drugs included in the illustrative list prepared by UNIDO in consultation with WHO, presided over by C.V.S. Mani (India).

Adoption of the report

12. The report, including the reports of the Working Groups, was adopted on Friday, 5 December 1980. Owing to the illness of the Chairman, the last session was presided over by João Chaves Rosa (Portugal).

Documentation

13. Documents for the First Consultation are listed in annex II.

Death of the Prime Minister of Portugal

14. On Thursday, 4 December 1980, the Prime Minister of Portugal, Dr. F. de Sá Carneiro, was killed in an air crash. The two Working Groups were in session that day and the participants in those Groups observed one minute's silence.

II. THE GLOBAL STUDY ON THE PHARMACEUTICAL INDUSTRY

15. The secretariat presented to the plenary the Global Study on the Pharmaceutical Industry as a background document. The Study examined the current situation of the pharmaceutical industry in developed and developing countries, the constraints on the growth of the pharmaceutical industry in developing countries, the prospects for the development of that industry by the end of the century, and the increasing need for international co-operation.
16. The Study outlined the alarmingly low production and consumption of pharmaceuticals in developing countries, and the increasing prices of intermediates and heavy burden imposed on the balance of payments of those countries by the import of drugs.
17. In spite of the rapid growth of the pharmaceutical industry in some developing countries, most of them had not yet started packaging or formulation operations, while others with adequate infrastructure and human resources were not yet engaged in basic production of bulk drugs.
18. In reviewing the major problems faced by developing countries in the sector, the Study outlined policy options such as preparation of essential drug lists, establishment of a system of central procurement, government policies to stimulate domestic production, and involvement of the public sector in production of pharmaceuticals.
19. The Study examined the existing wide disparities and fluctuations of prices for bulk drugs on the international market, pricing and availability of intermediates and raw materials as well as the availability, terms and conditions for transfer of technology.
20. The Study elaborated some aspects of research and development and emphasized the necessity of assisting developing countries to gradually establish domestic research and development capacities.
21. The Study stressed the importance of co-operation between developed and developing countries, emphasized the need for increasing co-operation among developing countries, and attempted to identify potential areas for such co-operation.

22. The participants commended UNIDO on the preparation of the Global Study on the Pharmaceutical Industry. Many participants considered that the Study gave an objective picture of the current situation of the pharmaceutical industry and of the main problems faced by the developing countries in that field. Other participants, however, felt that the Study contained several contradictions and inaccuracies.

23. One delegation submitted a written statement recommending the convening of an international group of experts to improve and modify the Global Study on the Pharmaceutical Industry for the Second Consultation.

24. The participants from a group of countries submitted a conference paper to the Bureau of the Consultation, expressing their comments and reservations on several aspects of the Study. It was stated that those were:

(a) Insufficient substantiation of facts and assessment of the role of the large pharmaceutical houses of the industrialized countries in the development of the pharmaceutical industry in developing countries;

(b) Insufficient understanding of the role of the free market system and the benefits that could be obtained therefrom by developing countries;

(c) Insufficient appreciation of the importance of patents and trademarks in providing incentives for research and development;

(d) Unbalanced assessment of the advantages and disadvantages of the establishment of central procurement systems by developing countries;

(e) Incorrect and imprecise statements, and statistical evidence given without indication of sources;

(f) Inclusion of a number of emotive statements.

25. In conclusion the paper submitted by that group of countries recommended a review of the conclusions of the Study.

26. In response to that conference paper, participants from another group of countries submitted for circulation a brief conference paper, the main points of which were as follows:

(a) The Study tackled the problems in the correct perspective in the context of health for all by the year 2000;

(b) The Study rightly stated that the marketing of similar or identical products under different brand names at different prices resulted in unhealthy competition and higher prices for the consumer;

(c) The statements in the Study relating to the insufficient linkage between orientation of research and development by the large pharmaceutical houses and prevailing diseases in developing countries were substantiated;

(d) The statements in the Study related to the exorbitant prices and the short supply of highly essential drugs for developing countries were objective;

(e) The Study mentioned resources applied on expensive drugs that were only marginally useful or even irrelevant to the solution of developing countries' needs to which UNIDO had done well to draw attention;

(f) The conclusions of the Study (pages 103-108) were well considered and needed no revisions.

27. Also in response to the first conference paper, a brief conference paper was submitted for circulation by the leader of the Indian delegation. His paper emphasized the following:

(a) The statement in the first conference paper that health enjoyed a lower priority than defence in India was not substantiated. Total expenditure on health care in the Plan as well as non Plan accounts was comparable with expenditure for defence. The Consultation, however, was hardly an appropriate forum to refer to such expenditure;

(b) The statement explained the objectives of the scheme of central procurement of drugs in India and pointed out that it resulted in sizeable price reductions for many drugs. That was strong evidence of success of central procurement, as rightly stated in the Study;

(c) The statement indicated that it was one-sided to say that production and utilization of some medicines in India had made heavy losses that were an additional burden to the tax payer. Keeping in view the public interest, and in order to make the most essential drugs accessible to the largest segment of the population, those prices had deliberately been kept low by the Government for many years.

III. ISSUES RECOMMENDED BY THE GLOBAL PREPARATORY MEETING

Issue 1. The pricing and availability of intermediates and bulk drugs

28. In introducing the issue paper (ID/WG.331/4) to the plenary, the secretariat stated that UNIDO had formulated two price schemes: the first was for intermediates, the high price of which was a major limitation on the development of the pharmaceutical industry in the developing countries; the second was for bulk drugs because it was felt that they should be available to pharmaceutical formulation units at stable prices during a specific period. In that connection, a long-term contract based on a formula with appropriate allowance for escalation would be feasible if suppliers could agree upon indicative prices for bulk drugs. The scheme formulated by UNIDO used indicative prices for bulk drugs based on the yearly average price for the year preceding the contract. The secretariat stated that the price and availability of bulk drugs were very important and that a consensus on those issues at the Consultation would facilitate the development of the pharmaceutical industry in the developing countries.

29. Many participants stated that there were wide disparities in the prices of bulk drugs on the international market. They indicated that the high prices of intermediates, and their faster growth, compared to those of the final products, hindered the development of the pharmaceutical industry in the developing countries.

30. Some participants stressed the importance of the free play of market forces in determining prices, and stated that when assessing price levels, the quality and reliability of the supply of the products should be taken into account. They also pointed out that the prices of intermediates were directly affected by the high prices prevailing in the petrochemical industry. Another participant, however, stated that when there were only three or four major suppliers perfect competition could not prevail.

31. There was a difference of opinion as to whether the adoption of a central procurement system had resulted in reduced prices of bulk drugs.

32. One participant emphasized the importance of promoting co-operation among developing countries particularly with reference to the transfer of technology and research and development activities.

33. In answer to a question, the secretariat replied that the document (ID/WG.331/4) had been prepared on the basis of information supplied only by developing countries because there had been no response from others.

34. The First Consultation agreed that a committee on pharmaceuticals should be set up under the auspices of UNIDO (para. 1).

35. There was a consensus on entrusting UNIDO with the preparation of a directory of sources of supply of essential drugs from both developing and developed countries.

Issue 2. Contractual arrangements for the production of drugs

36. The secretariat introduced two documents to the first Working Group on the contractual arrangements for the production of drugs: "Relevant issues to be taken into account when negotiating a transfer of technology agreement" (ID/WG.331/2 and Add.1) and "Preparation of guidelines" (ID/WG.331/1 and 3).

37. The secretariat indicated that those papers had been prepared in accordance with the recommendation of the Preparatory Meeting in Cancun. The second paper dealt with certain controversial issues and it contained possible texts for clauses in transfer of technology agreements.

38. In connection with industrial property legislation, many participants agreed with the view presented in the document that the current structure of the patent system was an obstacle to the development of the pharmaceutical industry in developing countries. A few participants cited cases of individual countries where the limitation or abolishment of the patent protection of pharmaceuticals had allowed the emergence and growth of a national pharmaceutical industry. Some participants drew attention to the differing degrees of protection granted to pharmaceuticals under national legislation and to the fact that some developed countries introduced product protection only when the industry had been developed. Several participants expressed their belief that patent protection hindered free competition and the possibilities of national industries to compete with international companies in national markets.

39. Several participants stressed the importance of the patent system and its contribution to the development of the pharmaceutical industry in their countries. They stated that the lack of patent protection would hinder innovation, transfer of technology and investments in the industry. Several participants added that the patent system contributed significantly to the diffusion of information on new discoveries in the field.

40. One participant recalled that WIPO had developed a model law on patents and inventions for developing countries.

41. Regarding fiscal and other legislation, some participants stressed that the conclusion of transfer of technology agreements must be based on acceptable terms and conditions and that the intervention of governments should be kept to a minimum.

42. Some participants indicated that the regulation of transfer of technology agreements and industrial property were matters to be decided by each country in accordance with its national economic and social objectives.

43. Several participants considered that problems connected with the health sector infrastructure and health care delivery system were not sufficiently covered in the documentation delivered to the Working Group.

44. The health sector infrastructure was considered by all participants to be of paramount importance for securing health care for the populations of their countries and for effective transfer of technology. Several participants indicated, however, that the existence of a well-established health sector infrastructure should not be regarded as a precondition for the transfer of technology or for the establishment of production facilities.

45. One participant was of the opinion that consumer health education was necessary in order to increase the awareness of the role and limitations of the use of medicines, and that the protection of the environment and the workplace should be a part of technology transfer. A substantial awareness of the importance of that matter was evident.

46. Several participants emphasized the importance of training as a necessary element for successful transfer of technology.
47. Several participants, referring to the issue of economies of scale, were of the view that national priorities, strategic reasons or the need to secure health care might overrule purely economic considerations. Other participants felt that the attainment of economies of scale was an important consideration in embarking on the setting-up of pharmaceutical units.
48. Some participants indicated that economies of scale was not a relevant consideration regarding the production of formulations. As regards the manufacture of bulk drugs, economies of scale was not always the decisive factor, but it could be more important in the case of the production of intermediates
49. A participant proposed that the secretariat should carry out case studies of success stories of pharmaceutical industries in developing countries. Another participant suggested that the secretariat should undertake more detailed analyses on the relevant issues to be taken into account when negotiating transfer of technology agreements.
50. Several participants pointed out that the UNIDO documents raised some issues that were the principal outstanding issues still to be resolved in the International Code of Conduct on Transfer of Technology being negotiated in Geneva under the auspices of UNCTAD. The same participants could not prejudice the positions their Governments might take on those issues during the intergovernmental negotiations on the International Code of Conduct and therefore had to reserve their position on the UNIDO documents.
51. The representative of UNCTAD explained that the United Nations Conference convened for the adoption of an International Code of Conduct on Transfer of Technology would resume its work in March 1981. He also pointed out that the treatment of issues in the documents prepared by the secretariat of UNIDO was not in contradiction to the draft Code.
52. In view of the information provided by the representative of UNCTAD concerning the absence of any contradiction between what was being done under the auspices of UNCTAD and what was being done under the auspices of UNIDO, some representatives emphasized that the discussions could continue.

53. It was also stated that the intergovernmental nature of UNCTAD gave it a guiding role in the field concerned. Taking into account the hierarchical difference existing at the legal level between a major UNCTAD intergovernmental and negotiating conference and a UNIDO Consultation, a representative stressed that while UNCTAD could draw up a framework text concerning the transfer of technology, UNIDO, meeting at a Consultation on the Pharmaceutical Industry, was in a good position to deal with problems specific to that industry.

54. One participant was of the opinion that conditions in every agreement varied according to the product and financial, intangible and other factors, and that therefore it was not possible to set out universally applicable clauses. He also stated that some of the draft clauses included in the document under discussion were misleading and ambiguous and would create disputes between the parties.

55. Some participants pointed out that through the granting of a licence the supplier created a competitor, and it was unrealistic to think that innovators would be willing to transfer technology without any restrictions, particularly with regard to markets to which the licensee could export.

56. Several participants felt that regulations on transfer of technology should be flexible, take the interest of the parties and of the acquiring country into consideration, and help to strengthen the bargaining position of the recipient party.

57. With regard to the confidentiality obligations and the sublicensing clause, some participants indicated that the consent of the supplying party was necessary to allow further disclosure of the technology or its transfer to third parties.

58. In connection with the export restrictions, some participants felt that such restrictions could hinder the possibility of establishing a pharmaceutical industry in developing countries that would operate efficiently.

59. One participant stated that contracts should positively determine the country or region to which the recipient could export. In any case, the supplier should not compete with the recipient in the acquiring country.

60. One participant, supported by others, stated that several references to the proposals and positions of the Commission of the European Communities (EC) (ID/WG.331/3) were correct. However, any analogy or extension of EC legislation to current international situations were not the most appropriate in order to support certain analyses or assumptions as envisaged by the UNIDO secretariat in the above-mentioned document.

61. The UNIDO secretariat explained that references to EC Commission proposals and positions as well as to other legislations had been made with the sole purpose of illustrating the solutions proposed or adopted on the issues dealt with at the national and regional level. Such references were not intended to suggest an extension to the international level of any national or regional position.

62. One participant clarified that according to EC law, restrictions on exports to non-member countries were not illegal. Another participant indicated that the EC draft proposal for a block exemption regulation for patent licence agreements and ancillary know-how cited in the secretariat document only expressed the views of the Commission of the EC and that it was still under discussion between member countries.

63. One participant agreed with the view expressed in the document that it was the ethical and legal duty of the supplier to inform the recipient, completely and correctly and in due time, of the properties and effects of products involved in the agreement as well as of changes in the registration status thereof.

64. All participants shared the view that liability was an extremely important issue in transfer of technology agreements in the sector. Some participants stressed that both parties should be responsible for damages or losses emerging from the application of the technology, and emphasized the difficulty in proving the origin of faults in the application of the technology.

65. One participant indicated that the liability of the supplier should take into account his negligence to provide adequate information for the use of the technology.

66. Many participants indicated that it was unrealistic to suggest royalty rates and the duration of agreements for the transfer of technology in pharmaceuticals. Some participants were of the opinion that the price should be left to the free negotiation of the parties and that the establishment of maximum rates could deprive the innovators in the industry of incentives to transfer their technologies.

67. Some participants suggested that there could be minimum royalty rates and the duration should also be restricted. The recipient should be free to sublicense after the expiry of the agreement. It was also expressed by one participant that assuming that the supplier of technology would have equity participation in the unit receiving the technology, there might not be a need to agree to any royalty whatsoever, since the participant felt that the supplier of technology would be adequately compensated through sharing of profits.

68. Another participant suggested that, unless it was a 100 per cent subsidiary, such a denial of royalty would be unfair.

69. One participant stressed the necessity to gather information on prices and other conditions in transfer of technology agreements. The secretariat explained that UNIDO had established a system with the participation of 20 developing countries that were exchanging information in that area.

70. Two participants emphasized the importance of considering the cost reduction - for example of imported raw materials incorporated - of the final product in order to calculate the royalties to be paid to the supplier.

71. One participant reminded the Working Group of the work already undertaken by WIPO in the preparation of a "Licensing Guide for Developing Countries".

72. Some participants indicated the importance of brand names and other forms of identification in order to determine the liability of the producers.

73. One participant pointed out that while there were no product patents in existence with regard to the 26 drugs included in the list of essential

drugs prepared by UNIDO and WHO, there were still some process patents in force in connection with some of those drugs.

Issue 3. The availability, terms and conditions for the transfer of technology for the manufacture of essential drugs included in the illustrative list prepared by UNIDO in consultation with WHO

74. In introducing the issue papers (ID/WG.331/5 and 8) to the second Working Group, the UNIDO secretariat stated that the developing countries constituted large markets for the 26 essential drugs identified by UNIDO on some of which the patents had lapsed. However, they experienced difficulty in obtaining suitable technology, especially based on early intermediates and raw materials. There had been virtually no effective transfer of technology to developing countries in cases where the technology was held by a few companies or where the developing countries possessed the required infrastructure and a sufficiently large market, as in the case of the antimalarial drug chloroquine. Although some developing countries were the sole producers of medicinal plants, they were obliged to export the plants to the developed countries as they did not have access to the technology. The establishment of joint ventures was considered suitable for the transfer of technology, subject to certain conditions. In that connection, the strengthening of technical co-operation between developing countries and of the research and development base in those countries had been stressed.

75. There was general appreciation of the UNIDO document and the secretariat's efforts in focusing attention on the issue under discussion in the Working Group. On the basis of their experience, some participants supported the statement of the UNIDO secretariat and said that, although they had raw materials, infrastructure and markets, they could not initiate production of essential drugs due to the non-availability of suitable technology.

76. Some participants from developed countries, centrally planned economies and industry expressed their willingness to enable transfer of technology to developing countries, although some felt that it was for individual

companies to enter into bilateral negotiations. Those representatives were requested to give details of their offers to the secretariat.

A few participants gave written preliminary information concerning the drugs for which technology could be offered, and an international trade association gave a list of 49 offers of technology from international companies for the 9 priority drugs in the illustrative list produced by UNIDO. One participant stated that it was not possible to have uniform terms for technology transfer under his country's national law.

77. Some participants from developing countries inquired why binding clauses were included in technology transfer arrangements for chloroquine as referred to in the UNIDO document. The UNIDO secretariat replied that it was not customary for UNIDO to mention the names of countries and individuals in such cases.

78. Some participants from developing countries emphasized their belief in the need to remove restrictive import and export clauses in technology transfer arrangements and stated that joint ventures should be subject to the conditions stipulated in the UNIDO document. Some participants from developing countries inquired why no developed country was forthcoming in transferring technology for dapsone, essential for the treatment of leprosy, which is endemic in certain developing countries. A participant from a centrally planned economy informed the Consultation that technology for dapsone was available from his country.

79. Several participants highlighted the importance of technology for processing medicinal plants as well as of technical co-operation among developing countries.

80. At the end of the discussion, a consensus was reached on conclusions and recommendations (paras. 1 to 7).

Annex I

LIST OF PARTICIPANTS

Afghanistan

Khalil Moqadar, Lecturer, Faculty of Pharmacy, University of Kabul

Algeria

Moulai Bemiloud, Chef de Délégation, Vice-Président, Commission de nomenclature, Ministère de la santé, Alger

Pierre Chaulet, Professeur de Médecine, Institut des sciences médicales d'Alger

Messaoud Zitouni, Professeur

Rachid-Ramdan Denine, Professeur de Pharmacie

Badredoine C. Benkhelifa, Directeur général, Pharmacie centrale algérienne

Mansouf Douaifia, Directeur, Unité de production, Pharmacie centrale algérienne

Rahah Hamdane, Fonctionnaire, Production médicament, Pharmacie centrale algérienne

Hamid Mansour, Chargé d'études, Ministère des industries légères

Angola

Alfonso Cortes de Lemos, Chefe de Departamento

Sadi Nsambu, Pharmacien

Madalena Azevedo Santos, Técnico de Farmácias

Argentina

Sebastián Bago, Presidente de la Delegación, Laboratorios Bago, S.A.

Hector Benedicto Blanco, Roux-Ocefa, S.A.

Amadeo Roberto Giustozzi, Centro Industrial de Laboratorios Farmacéuticos

Roberto Gold, Centro Industrial de Laboratorios Farmacéuticos

Hernán López Bernabó, Laboratorio Bernabó S.A.

Liria Angelina Remedi, First Secretary, Argentine Embassy, Portugal

Austria

Heinz H.D. Schneider, CHEMIE LINZ, Lic. Manager

Bangladesh

Anisul Islam, General Manager, Albert David (Bangladesh) Ltd.

Belgium

L. Molle, Directeur, Laboratoire de chimie analytique et de toxicologie,
Université de Bruxelles

C.R.O. Van Herpe, Conseiller, Ministère Santé Publique, Cité administrative
Bruxelles

Bhutan

R. Chhetri, Assistant Director, Department of Industries and Mines

Brazil

H.T. Cardoso, Scientific Technical Adviser, ABIFARMA

Marta Nobrega Martinez, Chemical Engineer, STI/MIC

José Coutinho do Nascimento, Head, Pharmaceutical and Chemical Industry,
Conselho Desenvolvimento Industrial, MIC

Cape Verde

Judith L. Oliveira, Director General, Empresa Nacional Medicamentos
(EMPROFAC)

Maria Antonia Bettencourt Pinto Monteiro, Directora do Laboratorio de
Controle de Medicamentos

China

Hongyun Guo, Senior Engineer, The State Pharmaceutical Administration
of China

Meizhen Jin, Department Head, China National Pharmaceutical Industry
Corporation

Tianyou Zhang, Engineer, Foreign Affairs Bureau, The State
Pharmaceutical Administration of China

Colombia

Francisco Barberi, Presidente INFACOL, (Industria de Farmacéuticos Nacionales)

Esterlina Gordillo, Jefe, Control de Costos y Precios, Ministerio de Salud

Cuba

Luis R. Capo, Director, Proyectos Industriales, Ministerio de Salud Pública

Democratic Yemen

Ahmed Abdo-Rubo, General Manager, National Drug Co.

Denmark

Holger Larsen, Secretary, Specialworkers in Denmark

Erik Farso Madsen, Counsellor of Embassy

Niels Ostergaard, Director, DUMEX Limited

Dominican Republic

Rosalda Damiano, Directora Científica, FARCARIIBE/ICOR

Egypt

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

Zakaria Ibrahim Gad, Under-Secretary of Health, Ministry of Health

Finland

Kai Granholm, Secretary of Embassy, Embassy of Finland

Matti Valanki, Orion Corporation Limited

France

M.L. Barreteau, Chef de délégation, Ministère de l'industrie

Etienne Barral, Economiste, Société Rhône-Poulenc

Hervé Bolot, Représentant permanent adjoint de la France auprès de l'ONUDI



India

Cadangode Venkatesnara Surra Mani, Additional Secretary,
Ministry of Health

Prasanta Kumar Ghosh, Project Officer (Drugs), Department
of Chemicals and Fertilizers,
Ministry of Petroleum Chemicals and Fertilizers

Indonesia

Heman, Project Manager of Essential Drugs Production
Directorate General for Drugs and Food Control,
Ministry of Health

Utarto Utomo, Managing Director, P.T. Kimia Farma
Isnenni Reksodidjojo, Import Manager, Kimia Farma

Ireland

E. Joseph Dover, Director-General, Federation of Irish Chemical
Industries

Italy

Domenico Muscolo, Director, Farindustria
Edoardo Montagna, Vice-President, Farindustria
Romano Capasso, Inspector-General, Ministry of Health
Jan Eibenschutz, Farindustria

Kenya

Besrat Hagos, Dava Pharmaceuticals Ltd.
Zlatko Rostocil, Dava Pharmaceuticals Ltd.
Samuel Maina Kiruthu, Projects Officer, Industrial Promotion
Department, Ministry of Industry

Liberia

Fred K.H. Gordon, Administrator, Pharmaceutical Services

Libyan Arab Jamahiriya

I. Abougela, Lecturer
Said Ghasem, Head of Pharmacy and Drug Research, Sec. of Health
Mohammed Said Shubair, Chairman, Department of Industrial Pharmacy,
Al-Fateh University

Malawi

Samuel Eddie Chalira, Chief Pharmacist, Malawi Pharmacies Ltd.

Mali

Boukassoum Haidara, Directeur, Pharmacie d'Approvisionnement du Mali

Malaysia

Keong Piau Wong, Deputy Director, Malaysian Industrial Development Authority

Mauritania

Taki Cheikh Brahim, Pharmacien Gestionnaire. Pharmarim

Mauritius

Mookteswar Ramdane, Managing Director, Mauritius Pharmaceutical Manufacturing Company

Mexico

Francisco José Viliesid Alonso, Researcher, LANFI

Enrique Del Val-Blanco, General Director. Federal Procurement

Angel G. Ordieres, Gerente General Farmacias,
Secretaría de Salubridad y Asistencia

Alejandro Bejar, Mexican Pharmaceutical Laboratories Chamber

Hernández Eduardo Fernández, Director General, Camara Nacional
Industria Farmacéutica

Efren Franco Díaz, SECOM

José Pablo Martínez Del Rio, Jefe de Investigación Económica, SEPAFIN

Alberto Mayoral, Subdirector, General Industria Química, SEPAFIN

Luis Eguiarte Pérez, General Co-ordinator, PROQUIVEMEX S.A.

Juan López Silanes, Vice-President, Confederation of Mexican Industry

José Antonio Suárez, President, Mexican Federation, FAQUIFARMEX

Fernán Ramon Fernández-Viana, Co-ordinator of Interministerial
Commission on Pharmaceutical Industry, Ministry of Industries

Ernesto Favela Alvarez, Director de Laboratorio Salubridad,
Secretaría Salubridad

Mexico (cont'd)

Juan Garibay, Subdirector Estudios y Proyectos de la Dirección General de Promoción Fiscal, Secretaría de Hacienda y Crédito Público

Enrique Gruner, President, Sección Fabricantes Farmoquímicos, Cámara Nacional Ind. Transformación, Quinonas de México S.A.

Jesús Jiménez Villafuerte, Secretaría Comercio

Morocco

El Mokhtar Tazi, President du CNOP

Abdallah Lahlou Filali, Vice-Président, Conseil national des pharmacies

Jaouad Cheikh Lahlou, Conseil de l'Ordre Industrie

Mozambique

Elisio Rainha da Silva, Chefe da Delegação

Renato Pedro João Ronda, Assistente

Zacarias Rafael Chichava, Assistente

Netherlands

Leendert Solleveld, Department of International Organizations, Ministry of Foreign Affairs

Rudi Labadie, Special Adviser, Department Pharmacognosy, University of Utrecht

Teunis Paulus Hubert, Federation Netherlands Trade Union

Okko Gerardus Van Aardenne, Department of Economic Affairs, Division: Chemical Industry

Johannes C. Sanders, Adviser, Dutch Delegation for the Employers, Dutch Association for Pharmaceutical Industry

Nicaragua

José Gonzalo Calderón, Subdirector de Tecnología, Ministerio de Industria

Nigeria

Chukwuka Nwaekwu, Deputy Secretary (Chemicals), Federal Ministry of Industries

Pakistan

F.R. Yousuf Fazli, Deputy Director-General (Pharmacy)/Drugs Controller
Ministry of Health

Panama

Samuel Ernesto Alba Fhang, Director de la Sección de
Farmacias y Drogas

Peru

Gerardo Garrido, Presidente de la Delegación, SINQUISA
Rafael Fernández Stoll, Delegado Industria-farmacéutica (ALAFARPE)

Poland

Jerzy Steczniewski, Export and Foreign Co-operation,
Department Manager, POLFA

Portugal

Joao Antunes Bartolo, Director Geral das Industrias Química
e Metalurgica, Ministério da Industria e Energia
José Alvaro Chaves Rosa, Director Geral do Comercio Não Alimentar
Luis Caldeira Pires, Vice-President, APIFARMA
Isabel Maria Santos Costa, Secretaria
Fernando Seixas, Director Geral
Sebastião Alves, President, Pharmaceutical Group, ATRAL-CIPAN
Pires Amavel, Director de Serviços, Ministério da Industria e Energia
Carlos Bernardo Mendes Paulo, Administrator ATRAL-CIPAN, Av. Gomes
Pereira, 74
Lício Godinho, Administrador da SIF
Remy Freire, Observer, IPE
Margarida Falcão, Técnico Superior, DGIQM, Ministério da Industria e Energia
Edite Duarte, Division Head, Ministério da Indústria e Energia
Direcção Geral das Industrias Química e Metalúrgica
João Antunes da Costa Valente, General Export Director,
Pharmaceutical Group, ATRAL-CIPAN
Manuel Godinho de Matos, Director, Serviços da D.G. Saude
José Manuel de Caldas Lima, Director, Transfer of Technology Department,
Foreign Investment Institute
Victor Alves, Adido de Imprensa do Ministério da Indústria e Energia
Ana Maria Santos Costa, Investigadora, LNETI

Portugal (cont'd)

Ivan Villax, Hovione Lda., Sete Casas
O.S. Karim, Franco Farmaceutica, Lda.
M. Rita Varandas, Técnico Superior, IAPMEI, MIE
Manuel Rodrigues Carvalho, Empresario, IPE
Marco Antonio Monteiro d'Oliveira, Subdirector Geral
Ministerio da Indústria e Energia
José Campos Mouta, Técnico, Gabinete de Estudos e Planeamento, MIE
Ana Paula Félix, Fundo Fomento de Exportação
Fernão Vicente, Quatrum SARL.
Maria da Luz Bastos, Técnico
Pedro Ferraz da Costa, Presidente da Associação Portuguesa da Industria
Farmaceutica
Maria Inez Florencio, LEETI
Antonio P. Cravo, APIFARMA

Qatar

Mohammed Ibrahim Al-Hail, Chief Pharmacist, Ministry of Public Health
Hamed Anwar Abu-Shady, Pharmaceutical Expert

Romania

Ana Spataru, Dipl. Economist, CHIMIMPORTEXPOR
Ion Minea, Joint Romania Centre, Bucharest Office
Elena Dumitrescu, Chef Department, Centrale industrielle de médicament

São Tome and Principe

G.S. Lima Costa Fernandes, Técnica de Farmacia
Ana Maria Graca Nascimento Will Costa Cardoso, Técnica de Farmacia

Saudi Arabia

Al-Muhareb Muhareb Sayar, Director of Medical Supplies
Ministry of Health
Abdallah-Yahia Aljifri, Chamber of Commerce
Al-Yami Ali Mubarak, Chief of Pharmaceutical Affairs,
Ministry of Health

Senegal

Ali Cisse, Directeur de l'approvisionnement médico-pharmaceutique
et de l'équipement technique

Somalia

Abdirizak Osman Hassan, Dean, Faculty of Industrial Chemistry,
Somali National University

Spain

Jorge Iniesta Pons, Industria
Manuel Ruiz-Jarbo, Subdirector, General Ind. Farmaceuticas,
Ministerio Industria

Sudan

Ibrahim Mohamed Abu-Al-Futuh, Senior Consultant,
Industrial Research and Consultancy Institute
Kamil Abdel Rahim Mahgoub, Technical Manager,
Sudanese Chemical Industries

Sweden

Stig Wahlquist, AB.Astra
Göran Gustavsson, Head of Section, Ministry of Industry
Torc Johansson, AB.Astra
Karl Hugo Thelin, Group Vice-President, KABIVITRUM
John Gunnar Lönnquist, Secretary of Government Committee,
The Committee for Industrial Co-operation on Pharmaceuticals,
Ministry of Health and Social Affairs
Gun Werin, AB LEO

Switzerland

Ernst Vischer, CIBA-GEIGY Ltd.
Ernst M. Jucker, SANDOZ Ltd.
Juan Bernardo Becker, Representative, Swiss Bank Corporation
Johannes Manz, Counsellor of Embassy, Mission of Switzerland, Vienna

Syrian Arab Republic

Mohamad Saadi Hammami, Directeur du Laboratoire DIMAS

Tunisia

Ali Stambouli, P.D.G. Pharmacie centrale de Tunisie

Uganda

Justo V. Oidu, Pharmacist, Mulago Hospital

Union of Soviet Socialist Republics

Robert G. Glushkov, Deputy Director, All Union Chemical
Pharmaceutical Research Institute

United Kingdom of Great Britain and
Northern Ireland

Arnold Worlock, Wellcome Foundation

Joseph Hallowell, DHSS

David John Woods, Permanent Mission to UNIDO, Vienna

United Republic of Tanzania

Ally Suleiman Abdulla, Plant Production Manager

United States of America

Joseph M. Bernik, Vice-President and General Counsel,
Abbott International Ltd.

Edgar G. Davis, Vice-President, Corporate Affairs, Eli Lilly and Company

Brewster R. Hemenway, Alternate Permanent Representative to UNIDO,
United States Mission to UNIDO, Vienna, Austria

Leo R. McIntyre, Drug Industry Specialist, United States Department
of Commerce

Matthew W. Perry, Jr., Vice-President, Special Projects, Pharmaceutical
Manufacturers Association Member, US Group

Sheldon W. Samuels, Director of Health, Safety and Environment,
Industrial Union Department, AFL-CIO

Herbert J. Schneider, Secretary and Counsel, Rorer International Corp.

William E. Sykes, Group Vice-President Administration, Upjohn Co.

Venezuela

Hemilsy Abreu Burelli, Jefe de la Division de Industrias Químicas
en el Ministerio de Fomento

Yugoslavia

Petre Liubarovski, Member of the Yugoslav Delegation, Adviser
to the General Manager, Alkaloid Skopje

Mihael Kremser, Member of the Yugoslav Delegation, Director
RD LEK, Pharmaceutical and Chemical Industry

Zaire

De Dobbeleer, Pharmacien Directeur du Laboratoire pharmaceutique de
Kinshasa, Département de la santé publique

United Nations Secretariat

United Nations Conference on Trade and Development (UNCTAD)

K. Balasubramaniam, Senior Pharmaceutical Adviser

United Nations Economic and Social Commission for Asia
and the Pacific (ESCAP)

Claudio Sepulveda, Co-ordinator, Project on Pharmaceutical
Industry in ASEAN countries (UNDP/UNICEF/ESCAP)

International Trade Centre (ITC)

Saeed Chaudhry, Market Development Officer

United Nations bodies

United Nations Children's Fund (UNICEF)

Hans Probst, Senior Procurement Officer

Specialized agencies

World Health Organization (WHO)

Fernando S. Antezana, Senior Scientist, Geneva

Istvan Bayer, Temporary Adviser, Regional Office for Europe, Copenhagen

World Bank

David Albert Caplin, Project Officer

Intergovernmental organizations

European Economic Community (EEC)

Vittorio Ghidi, Second Secretary, Delegation of the Commission of the EC to the International Organizations, Vienna

Non-governmental organizations

Arab Company for Drug Industries and Medical Appliances (ACDIMA)

Hashim I. Dhahir, Director-General.

Fédération Mondiale des Syndicats de l'énergie, de la chimie et des industries diverses (ECI)

Marcel Sommereyns, Secrétaire général, Centrale Chrétienne energie chimie

Federacion Latinoamericana de la Industria Farmacéutica (FIFARMA)

Oscar Pérez Diéguez, Secretario Ejecutivo Adjunto

Alejandro M.J. Comin, Member of the Council, Secretaría Ejecutiva

International Federation of Catholic Pharmacists (FIPC)

Jean Dreano, Président, Fédération Internationale des Pharmaciens Catholiques

International Federation of Pharmaceutical Manufacturers Association (IFPMA)

Hillibald Conzen, Schering-Plough Corp.

Otto Herbert Nowotny

Michael Peretz, Executive Vice-President

Shoji Matsui

Saurendra Kumar Bhattacharya, President, Organization of Pharmaceutical Producers of India.

Asociación Latinoamericana de Industrias Farmacéuticas (ALIFAR)

Mario Palenzona, Vice-President

Eduardo White, Secretaría General

Edgardo Nelson Ambrogio

Annex II

LIST OF DOCUMENTS

Information documents

Provisional agenda	ID/WG.331/7
Provisional list of documents	ID/WG.331/9

Main working documents

Issue 1

The pricing and availability of intermediates and bulk drugs	ID/WG.331/4
--	-------------

Issue 2

Relevant issues to be taken into account when negotiating transfer of technology agreements	ID/WG.331/2 and Add. 1
---	------------------------

· Preparation of guidelines:

Summary and main conclusions	ID/WG.331/1
Background paper	ID/WG.331/3

Issue 3

The availability, terms and conditions for the transfer of technology for the manufacture of essential drugs	ID/WG.331/5
--	-------------

· Illustrative list of drugs prepared by UNIDO in consultation with WHO	ID/WG.331/8
---	-------------

Background documents

Global study of the pharmaceutical industry ID/WG.331/6 and
Add.1

Reports and documents of preparatory meetings

Draft report of the Global Preparatory Meeting
for Consultations on the Pharmaceutical
Industry, Cancun, Mexico, 24-27 April 1980 ID/WG.317/3

Issues that might be considered at the
First Consultation ID/WG.317/1

Report of the Inter-Regional Meeting to
Prepare for Consultations on the Pharmaceutical
Industry, Cairo, Egypt, 23-27 January 1979 ID/WG.292/3

Assessment of the pharmaceutical industry
in developing countries, its potential and
the national and international action
required to promote its development ID/WG.292/2

The Growth of the Pharmaceutical Industry
in Developing Countries: Problems and
Prospects Sales publication,
No. 78.II.B.4 (ID/204)

Report of the Second Panel of Experts
on the Pharmaceutical Industry
Vienna, 28 February - 3 March 1978 ID/WG.267/4/Rev.1



