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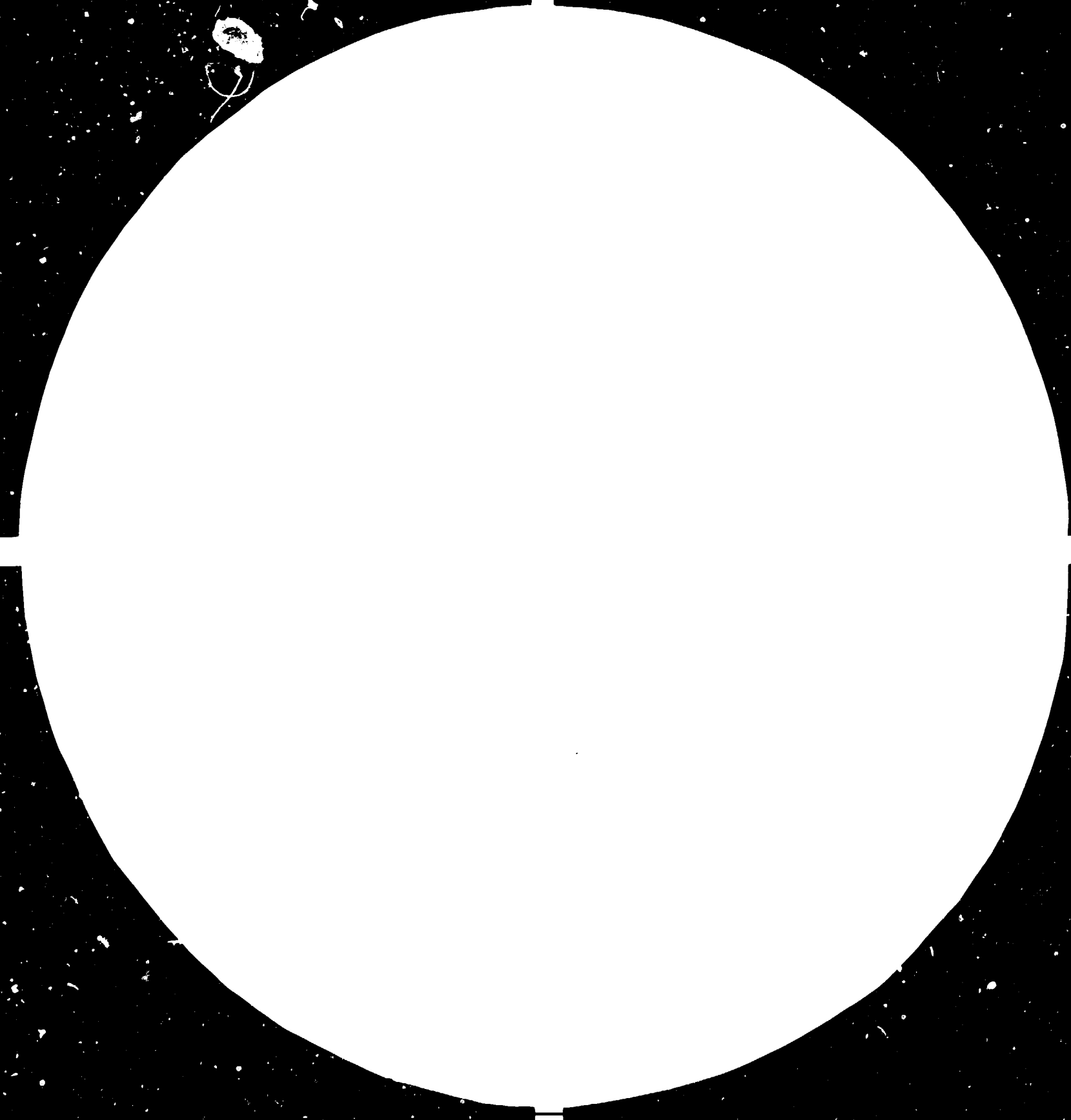
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UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

**SECOND
CONSULTATION
ON THE
PHARMACEUTICAL
INDUSTRY**

Budapest, Hungary, 21–25 November 1983

REPORT

(2nd Consultation on the pharmaceutical industry).

ID/311

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 share of the developing countries in world industrial output through increased international co-operation.^{1/} The General Assembly, at its seventh special session in September 1975, endorsed the recommendation and requested UNIDO to implement it under the guidance of the Industrial Development Board.

Twenty Consultations have been convened since 1977 covering the following industries and fields: capital goods, agricultural machinery, iron and steel, fertilizer, petrochemical, pharmaceutical, leather and leather products, vegetable oils and fats, food-processing, wood and wood products, industrial financing, and training of industrial manpower.

In May 1980, the Industrial Development Board decided to place the System of Consultations on a permanent basis, and in May 1982 it adopted the rules of procedure^{2/} according to which the System of Consultations was 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;^{3/}

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/ The System of Consultations (PI/84).

3/ Ibid., para. 1.

The System of Consultations would also permit negotiations among interested parties at their request, at the same time as or after consultations;^{4/}

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;^{5/}

Each Consultation shall formulate a report, which shall include conclusions and recommendations agreed upon by consensus and also other significant views expressed during the discussions.^{6/}

The Industrial Development Board, at its fifteenth session in 1981 decided to include the Second Consultation on the Pharmaceutical Industry in the programme of Consultations for the biennium 1982-1983.

4/ Ibid. para. 3.

5/ Ibid. para. 23.

6/ Ibid. para. 46.

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INTRODUCTION

Second Consultation

1. The Second Consultation on the Pharmaceutical Industry was held at Budapest, Hungary, from 21 to 25 November 1983. The Second Consultation was attended by 215 participants from 66 countries, and by 18 observers from 12 international organizations (see annex I).

Background to the Second Consultation

2. As a follow-up to the recommendations of the First Consultation on the Pharmaceutical Industry held at Lisbon, Portugal, UNIDO undertook in 1981:

(a) To convene a round table meeting on the development of the pharmaceutical industry to advise UNIDO on the actions to be taken to implement the recommendations of the First Consultation, including the compositions of the Committee of Experts and the Ad hoc Panel of Experts;

(b) To carry out a survey on drugs for which technology could be offered.

3. The Round-table Meeting on the Development of the Pharmaceutical Industry (UNIDO/PC.33) was convened in Morocco in December 1981. It arrived at the following conclusions and recommendations:

Issue 1: Availability and pricing of essential bulk drugs and intermediates

(a) The Committee of Experts to be established should pay particular attention to those bulk drugs and intermediates for which there were only limited sources of supply, which according to the UNIDO list, was 9 of the 26 essential drugs;

(b) The Committee of Experts should include representatives from those manufacturers of bulk drugs and intermediates for which there were limited sources of supply;

(c) UNIDO should prepare a directory of sources of supply of the 26 essential drugs and their intermediates, including details and specifications. The directory should be updated periodically.

Issue 2: Contractual arrangements

(d) Guidelines, and the main principles to be considered in the preparation of documents on contractual arrangements, were recommended as well as other items that should be included in such arrangements;

(e) The composition of the Ad hoc Panel should be kept small, not more than 12;

(f) The scope of the study on "relevant topics to be taken into account when negotiating transfer of technology agreements" was defined.

4. Following the advice of the Round-table Meeting, the Committee of Experts was convened in Paris, France, in October 1982, and adopted conclusions and recommendations (UNIDO/PC.59, paras. 7 to 11), a copy of which was circulated to the Second Consultation. The Ad Hoc Panel of Experts met at Vienna, Austria, in December 1982 and April 1983 (ID/WG.385/4 and UNIDO/PC.62). A meeting on co-operation between developing countries was convened at Tunis, Tunisia, in September 1983, to define the scope of their co-operation (UNIDO/PC.76).

AGREED CONCLUSIONS AND RECOMMENDATIONS

Issue 1: Contractual arrangements on the production of drugs
(ID/WG.393/6 and 7)

Conclusions

5. The Consultation took note of the three documents (ID/WG.393/1, 3 and 4) worked on by the members of the Ad Hoc Panel of Experts and submitted to the Consultations, and of the complete support expressed for them by the developing countries. It considered those documents to be of great value. However, the Consultation was unable to reach full agreement on them because of differences of opinion on certain points of those documents.

Recommendations

6. 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 the 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.

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

Issue 2: Availability, pricing and transfer of technology
for bulk drugs and their intermediates

Conclusion

8. The Consultation was of the view that where a country decides to establish or expand manufacturing or formulating capacity of specific products it was appropriate for UNIDO to make available advice and assistance in the selection and acquisition of technologies, preparation of feasibility studies, obtaining of investment finance and, more generally, establishment of manufacturing capacity including the training of manpower.

Recommendations

9. UNIDO had received certain offers of technology for the production of intermediates and bulk drugs but, since these did not cover all the 26 essential drugs on the UNIDO illustrative list, the Consultation recommended:

(a) That information already available in UNIDO regarding technology holders who are willing to transfer technology should be updated and circulated as soon as possible;

(b) That the questionnaire circulated earlier should be simplified, validated and recirculated by UNIDO. The additional information thus received from technology holders should be consolidated and circulated by UNIDO as quickly as possible;

(c) That, in respect of offers of technology for the production of intermediates and bulk drugs, UNIDO should, in co-operation with technology holders, prepare feasibility studies at the request of interested countries;

10. The "Directory of sources of supply of 26 essential bulk drugs, their chemical intermediates and some raw materials" (ID/WG.393/2), which is a list of basic producers and their direct selling agents, should be:

(a) Revised and widely distributed to interested countries not later than 1 January 1985 and thereafter brought up to date annually;

(b) Enlarged progressively to cover the full WHO model list of essential drugs;

11. UNIDO should undertake a study examining suitable ways in which help can be given to interested countries to improve their management skills for the procurement of finished and bulk pharmaceuticals and intermediates. It should include in its study available public sources of information on levels of prices for such materials.

12. In order to facilitate the establishment of formulation and packaging units in the least developed of the developing countries, the technical profiles (ID/WG.393/14) submitted to the Consultation should be completed and made available for the information of those countries to enable them to initiate measures necessary for the development of their pharmaceutical industries.

13. In order to support the efforts of developing countries to formulate national industrial drug policies with particular reference to pharmaceutical production, the experience of developed and developing countries available in

the form of studies already produced in United Nations agencies should be studied by UNIDO and relevant factors having a bearing on industrial drug policy should be extracted and circulated to developing countries. (This is not intended to provide a mandate for UNIDO to make policy recommendations to member countries on the issue of the formulation of industrial drug policy.)

14. UNIDO should both continue and strengthen its co-ordination and co-operation with WHO, FAO and other international organizations of the United Nations System in order to ensure that the work of these organizations in the field of manufacture of pharmaceuticals and vaccines is complementary.

15. The Consultation agreed that UNIDO might, at the request of interested Governments, undertake a feasibility study and subsequently convene an intergovernmental meeting to consider the establishment of a process research and development centre (which, inter alia, would provide services to interested countries in acquiring and assessing technologies for their pharmaceutical sector, development of manufacturing processes to fit their specific needs, provide reference quality control for raw materials intermediates and bulk drugs, and help to develop the medicinal plant industry and organize training course). It was understood that work on that proposal should be financed from funds available to the interested Governments.

Issue 3: The development of drugs based on medicinal plants

Recommendations

16. The Consultation recommended that UNIDO should:

(a) Initiate the compilation of both a data base and a directory on plants used as therapeutic agents containing all available information pertinent to their use or for the extraction of their active principles;

(b) Convene an expert group meeting to advise UNIDO with regard to this undertaking and to outline the steps to be taken in future programmes with regard to the transfer of technology for the genetic improvement of medicinal plants and their processing;

(c) Develop guidelines to assist developing countries to accomplish the improved supply of medicinal plants as raw materials or as processed products;

(d) Continue to encourage and promote active collaboration between developing countries and between developed and developing countries in all areas concerning the better industrial utilization of medicinal plants and the development of the pharmaceutical industry for medicinal plants;

(e) Intensify its training programmes, workshop and pilot plant installations in relation to the medicinal plant industry, to enable developing countries to rapidly acquire skills and expertise on manufacturing process know-how, pharmacological and chemical standardization of active plant constituents and quality assurance;

(f) Play an intermediary role in the transfer of technology, to developing countries for the industrialized countries.

Issue 4: Biologicals

Conclusions

17. The Consultation, recognizing that vaccination programmes are essential to the health of the population particularly of developing countries, agreed that the following were of major importance:

(a) The transfer of technology could be offered in stages:

- (i) The first stage must be the creation and the running of a validated national quality control facility and a national quality assurance programme;
- (ii) The second could include the transfer of technology of vaccine blending, filling and packaging. A precondition for that type of technology transfer was often the purchasing of bulk vaccine

from the technology supplier. As a preliminary stage, the setting-up of an infusion and reconstituting fluids plant could be crucial in order to assure the transfer of technology for the water treatment process and sterile operation:

(iii) The third would be a step-by-step approach assimilating technologies from filling and packaging to actual manufacture and from the production of classical vaccines to modern ones. Joint ventures were advisable only if there were industrialized production technologies. Production facilities could be developed at subregional or regional levels to achieve economic feasibility;

(b) The vaccines thus produced must comply with WHO requirements.

18. It has to be taken into account that the production of vaccines differs significantly from other pharmaceutical products in that:

(a) The problems of storage and distribution were crucial and a continuous cold chain was essential;

(b) The products were rarely subject to patent protection, and established production facilities had the capacity to ensure an adequate supply to the developing world;

(c) In an immunization programme, the cost of the product was a minor item in relation to the overall cost, and the success of such a programme was entirely dependent on adequate infrastructure for distribution and administration.

19. A further step in the transfer of technology was the treatment of local blood on a regional basis in order to take into account the differences in epidemiology.

Recommendations

20. It was recommended that UNIDO should take the following actions:

(a) Use the distinction of classical and modern vaccines for practical purposes, as classified in ID/WG.391/12/Rev.1;

(b) Consider the addition of vaccines, sera (both for human and veterinary use) and immunoglobulins to the existing biologicals in the UNIDO illustrative list;

(c) Adopt a step-by-step approach for establishing control and production capability of vaccines in two ways:

- (i) From filling and packaging towards actual manufacture;
- (ii) From production of classical vaccines towards modern ones;

(d) Implement long-term continuous technical assistance and support programmes for effective assimilation of technology and control procedures to be transferred;

(e) Promote the transfer of technology for modern vaccines at national and regional levels where there is adequate technical infrastructure;

(f) Promote the manufacture at regional level of certain biologicals other than vaccines that are either difficult to procure or only used in developing countries.

I. ORGANIZATION OF THE CONSULTATION

Opening of the Consultation

21. The Second Consultation on the Pharmaceutical Industry was opened by the Executive Director of UNIDO. He thanked the Minister of Industry of the Government of Hungary for the Government's hospitality, and welcomed the participants to the Consultation.

Speech by the Minister of Industry, Government of Hungary

22. The Minister of Industry, on behalf of his Government, welcomed the participants to Hungary. He said that his Government had always supported progressive and democratic endeavours to establish a new economic order in the world. It was in accordance with the objective of the Second General Conference of UNIDO that the share of the developing countries in the world's industrial production should be increased through the strengthening of international co-operation. He said that the System of Consultations was a highly effective way of developing such co-operation. Certainly there would be issues on which no agreement would be reached at the Consultation, but it was also certain that positions would be brought closer together. Hungary believed that such international co-operation should be based on the principle of equality and mutual advantages. Accordingly, it had transferred technology and expertise to the developing countries. It also envisaged more intensive forms of co-operation such as in production, agreements on relocating the manufacture of some products in the developing countries and the establishment of joint ventures.

23. His Government had signed technological and scientific co-operation agreements with 43 developing countries, sending experts to those countries and offering them educational and training facilities in Hungary. It had also co-operated in UNIDO seminars and expert meetings.

24. He said that Hungary derived almost 50 per cent of its income from foreign trade. He deplored the current international economic and financial situation, which was not favourable to bringing about a new economic order or to the industrialization of the third world countries. The developed countries had also been affected, and Hungary was no exception. Particularly in view of the current situation, international representatives should get together to exchange views on problems, including those of developing the pharmaceutical industry in the developing countries. In such a way, partners would find areas of common interest and identify mutual advantages. The development of the pharmaceutical industry was more than a question of industrial policy, it also greatly concerned public health and social policy. He wished the Consultation every success.

Speech by the Executive Director

25. The Executive Director said that UNIDO was placing increasing emphasis on activities that served the basic needs of people in developing countries. It followed therefore that the Industrial Development Board of UNIDO had decided to give prominence to the pharmaceutical industry. Because that industry had an impact on almost every facet of society, it was justifiably considered by many developing countries to be a strategic area of development.

26. The issues of health and disease were as important as those of food and hunger although not as emotive. The developed countries had made remarkable progress in medical diagnostics and treatment that should be equally available in the third world. He noted that, at the present time, developing countries spent \$US 5.5 billion per annum on medicaments, and that that amount was expected to increase to \$US 9 billion in 1985. The developed countries produced 89 per cent of the world output of pharmaceuticals; the developing countries, in contrast, had little or no capacity for the basic manufacture of drugs. That situation had to be changed through the promotion of the pharmaceutical industry in those countries.

27. The Executive Director spoke of the efforts of UNIDO. It had established two groups of experts, one to consider pricing and availability of bulk drugs and their intermediates, the other to consider contractual arrangements for the production of drugs.

28. In connection with the work of those two groups, the UNIDO secretariat had found it desirable to submit two new issues to the Consultation: one relating to the production of vaccines in developing countries, the other to the production of purified extracts from medicinal plants. In connection with the second, he had established the Advisory Expert Group on Preventive Medicines to advise UNIDO on its technical co-operation programmes for the production of such medicines in developing countries.

29. In conclusion, he recognized that, in that complex industry, powerful and often diverse interests were involved, but he felt confident that the Consultation would reach positive results.

Speech by the Deputy Director of the Division of Policy Co-ordination

30. The Deputy Director of the Division of Policy Co-ordination and Head of the Negotiations Branch spoke of the System of Consultations and its place within the framework of other UNIDO activities. He drew the attention of participants to UNIDO programmes related to technical co-operation, industrial studies, technology, investment promotion and the System of Consultations.

31. He recalled that the System was based on a decision adopted by the General Assembly at its seventh special session and that it was therefore supported by all Member States. The rules of procedure had been adopted by the Industrial Development Board after lengthy discussions and hard negotiations. Among the objectives of the System of Consultations was the search for action-oriented measures towards increasing the share of developing countries in world industrial production.

32. The approach adopted to Consultations was one of quasi-permanent concerted action both before and after a given Consultation. To that end, 10 meetings were convened before and after the First Consultation on the Pharmaceutical Industry. The documents submitted to the Second Consultation reflected therefore the point of view of experts and participants from a wide range of both developing and developed countries.

33. Given the complexity of the pharmaceutical industry, UNIDO had involved experts in that field selected on the basis of equitable geographical distribution, as well as representatives of international organizations. He recalled the invitation extended by UNIDO to the World Health Organization to co-sponsor the Second Consultation.

34. The Deputy Director then highlighted the four main characteristics of the System of Consultations. First, it counted on a wide participation including representatives of Governments, industry and labour. Secondly, decisions were taken on the basis of consensus both at the level of the plenary and of the bureau. Thirdly, recommendations were not obligatory in nature; he stressed that the secretariat's role was catalytic in nature and that it could never replace the role of the participants themselves. Fourthly, the report of a Consultation was composed of two parts: the summary of the main points discussed, and the recommendations of the Consultation that emanated from the deliberations of the working groups and that were adopted by the plenary at the end of the Consultation.

Election of officers

35. Edit Varga (Hungary), General Manager of Chemical Works of Gedeon Richter Ltd., was elected Chairperson of the Consultation.

36. Michèle Sauteraud (France), First Secretary, Permanent Mission of France to the International Organizations in Vienna was elected Rapporteur.

37. The following persons were elected as Vice-Chairmen:

- S. Stanev (Bulgaria), Associate Professor, Pharmachim-Sofia
- Ahmed Aboul-Enein (Egypt), Chairman, Chemical Industries Development
- S. Ramanathan (India), Secretary, Ministry of Chemicals and Fertilizers,
Government of India
- T.R. Weber (Mexico), Director General of Chemical Industries.

Adoption of the agenda

38. The following agenda was adopted:

1. Opening of the Consultation
2. Election of officers
3. Adoption of the agenda
4. Progress report on actions taken to implement the recommendations of the First Consultation on the Pharmaceutical Industry
5. Contractual arrangements for the production of essential drugs
6. Price and availability of bulk drugs, intermediates and transfer of technology for the manufacture of the drugs included in the UNIDO List of 26 Essential Drugs
7. Proposals for new issues:
 - (a) Medicinal plants
 - (b) Biologicals
8. Conclusions and recommendations
9. Adoption of the report of the Consultation

Establishment of working groups

39. The Consultation established two working groups to discuss the issues submitted for its consideration, and to prepare conclusions and recommendations for consideration at the plenary session. Working Group 1 covered the issue related to contractual arrangements, while Working Group 2 covered the availability, pricing and transfer of technology for bulk drugs and their intermediates, and also the issues related to medicinal plants and biologicals.

40. E. Vischer (Switzerland), Vice-Chairman of Ciba-Geigy S.A., was elected Chairman of Working Group 1, and G. Garrido (Peru), Director General, Sinquisa, was elected Chairman of Working Group 2.

Documentation

41. Documents issued for the Consultation are listed in annex II.

Adoption of the report

42. The report of the Second Consultation, including the conclusions and recommendations, was adopted by consensus in plenary on Friday, 25 November 1983.

II. REPORT OF THE PLENARY SESSIONS

Progress report on actions taken to implement the recommendations of the First Consultation on the Pharmaceutical Industry

43. In discussing agenda item 4, several participants made observations on specific points included in the Progress Report (ID/WG.393/5), concerning for example the insufficient way in which the results achieved by the Committee of Experts (UNIDO/PC.59), which met in Paris in October 1982, had been reflected therein. It was generally agreed that the discussion on that item could be pursued in the working groups.

Presentation of the issues

Issue 1: Contractual arrangements for the production of drugs

44. In introducing issue 1 (ID/WG.393/6), a representative of the UNIDO secretariat recalled the recommendation of the First Consultation on the Pharmaceutical Industry according to which UNIDO, in co-operation with an Ad Hoc Panel of Experts, was asked to prepare a document, complete with background notes, on the various terms, conditions and variations thereof that should be included in contractual arrangements.

45. He drew attention to the three main documents that the Ad Hoc Panel of Experts had produced in response to that recommendation: "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), "Items which could be included in licensing arrangements for the transfer of technology for the formulation of pharmaceutical dosage forms" (ID/WG.393/3), and "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).

46. It was emphasized that those documents had been agreed to by consensus by the members of the Ad Hoc Panel and were the result of long and hard negotiation.

47. The documents outlined three types of contractual arrangements, with emphasis on the most important and most difficult aspects. That approach had been found necessary in view of the complexity of the subject and the lack of time, and also to prepare a base for the preparation of more complete documents of general applicability. To achieve that objective, the Ad Hoc Panel had accepted that the document on licensing arrangements (ID/WG.393/3) would apply to the broader list of drugs contained in the WHO model list of essential drugs, and had recommended the preparation of two additional documents on turn-key contractual arrangements and on arrangements for technical assistance for the formulation of pharmaceutical forms.

48. He requested the guidance of the participants on further steps to be taken by UNIDO to improve or complete the three main documents with a view to evolving contractual documents of a more general applicability. He also sought their advice on the preparation of the two documents recommended by the Ad Hoc Panel.

49. The representative of the UNIDO secretariat also introduced the study entitled "Relevant topics to be taken into account in the preparatory phase of technology transfer arrangements for the production of pharmaceuticals" (ID/WG.393/17), which had been requested by the First Consultation.

50. A representative of the UNIDO secretariat presented issues 2, 3 and 4, and sketched in the background to those issues.

Issue 2: Availability, pricing and transfer of technology for bulk drugs and their intermediates

51. Issue 2 (ID/WG.393/8 and 9) concerned the disparity between the prices of bulk drugs and their intermediates, and the non-availability of technology for the production of the 26 essential drugs in the UNIDO illustrative list (ID/WG.393/9, annexure A), and their intermediates.

52. The Committee of Experts acknowledged the major impact of availability and pricing of intermediates in bulk drug production and dosage form formulations in developing countries. However, no conclusion or alternative approach resulted concerning the pricing mechanism that linked the cost of the intermediates to that of the drugs.

53. The Committee therefore recommended the production of intermediates and bulk drugs in developing countries through the transfer of technology. In that connection, it prepared a questionnaire to obtain non-confidential information relevant to the transfer of technology for the manufacture of those intermediates and bulk drugs. That questionnaire was sent to 130 major pharmaceutical producers in developed and developing countries. However, only 14 replies were received covering 17 drugs and 2 intermediates so it was not possible to prepare the study on transfer of technology requested by the First Consultation.

54. Since the problem of availability and pricing of intermediates remained unsolved, and the technology to manufacture them seemed unavailable, the desirable up-stream integration to produce such drugs from raw materials could not be achieved. The Second Consultation was therefore invited to consider whether the problems related to the pricing of intermediates could be solved through production or whether alternative approaches should be sought. Considering the intention of the Committee to solve that issue through production in developing countries, UNIDO had continued its search and was eventually successful in identifying some independent research-based technology holders willing to transfer technology for the production of some intermediates out of the 26 essential drugs in the UNIDO list.

Issue 3: The development of drugs based on medicinal plants

55. Issue 3 (ID/WG.393/10 and 11) concerned the importance of medicinal plants and their impact on the economies and the social welfare of the developing countries. The representative of UNIDO stressed the need for developing countries to complement expensive chemical drugs with cheaper plant-based drugs in order to provide health-care coverage to the majority of the population at reasonable cost. In addition, assistance to increase their supply of medicinal plant raw materials and to upgrade production from crude plant extracts to pure active principles would be necessary.

Issue 4: Biologicals

56. Issue 4 (ID/WG.393/12 and Rev.1, and 13 and Rev.1) covered the most urgent need for biologicals, that is the production of vaccines in developing countries. She said that infectious diseases preventable by immunization remained one of the greatest problems to be tackled by the developing countries but the vaccines were produced mostly in the developed countries. The interest of the developed countries in producing those vaccines could become less and less, causing concern in the developing countries that relied heavily on their import and donation. The developing countries should, therefore, create infrastructural capabilities for the production of those biologicals.

Summary of discussion

Opening plenaries

57. The experience in the pharmaceutical industry of several developed and developing countries was the subject of many statements. Some developing countries described their national efforts to establish and promote the production of pharmaceuticals. Important bases for such efforts were national research and development, the provision of training and adequate financial resources. One participant added that the adoption by his Government of an adequate drug policy had led to low pharmaceutical prices in his country. In the view of several countries, the acquisition of technology was a key element of international co-operation and continued to pose problems to the development of the industry.

58. Industrial co-operation was a subject on which many participants voiced their opinions. While some participants stressed the importance of co-operation based on the principles of equality and mutual advantage, others stressed that the operation of a free market was necessary for international co-operation to succeed. One participant stated that the prices of intermediates had to be determined in relation to world market prices for end-products. The important role played by direct foreign investment was underlined.

59. It was felt that there was still room for North-South co-operation to be expanded. Several participants stressed that their countries were already actively involved in providing assistance to developing countries through both bilateral and multilateral channels in the areas discussed at the Consultation. An observer from a non-governmental organization confirmed its willingness to contribute to the industrial growth of developing countries on fair and mutually acceptable terms, and expressed its sympathy with the industrialization objectives of developing countries.

60. On the subject of technology, one participant emphasized that there existed many technologies that were not legally protected; in his view, that was a large area in which there was scope for expanding co-operation between developed and developing countries.

61. Several participants stated that they were ready to make certain technologies available to developing countries and that they would provide the UNIDO secretariat with details of their offers. One participant stressed that the difficulties of transferring any technology differed with the different stages of production. A few participants underlined that before any drug technology could be transferred, an adequate distribution and quality control system had to be established. One participant stated that bilateral contracts between developed and developing countries varied according to local conditions and the technologies being transferred.

62. In connection with the transfer of technology, many participants considered that the provision of full training was of the utmost importance. One participant emphasized that developing countries were often unable to obtain the training they required in view of insufficient financial resources: he suggested that technical assistance in the field of training be provided in support of technology transferred through contractual arrangements. The First Consultation on the Training of Industrial Manpower, held in 1982, was referred to in that context.

63. The quality of the documentation submitted to the Consultation by the UNIDO secretariat was generally appreciated by participants. It was considered that the "Directory of sources of supply of 26 essential bulk drugs, their chemical intermediates and some raw materials" (ID/WG.393/2) provided a

welcome point of reference for those concerned with the pharmaceutical industry in developing countries; one participant suggested that that Directory be completed by the end of the year. Many participants requested UNIDO to ensure that the Directory be systematically updated and several suggested that it be expanded to cover all the essential drugs listed by WHO. One participant suggested that UNIDO also prepare a directory on the sources of technology. A few participants, however, thought that existing directories, published by other institutions, were sufficient to meet the needs of developing countries.

Closing plenary

64. One observer, in referring to the figures contained in the speech of the Executive Director of UNIDO expressed the view that annual expenditures of developing countries on medicaments would rise from \$US 16 billion to \$US 30 billion in 1985, and that the developed market economies were producing around 80 percent of the world output of pharmaceuticals.

65. There was a great deal of discussion as to whether the qualifying phrase: "if such consultation is authorized by the Industrial Development Board" to recommendations 7(d) and (e)(ii), as drafted by Working Group 1, should be retained. Many participants were in favour of deleting that phrase as they considered that the Second Consultation had been a unique occasion to discuss the problems of the pharmaceutical industry at a world level, and that the dialogue initiated should be pursued through the convening of the Third Consultation. The representative of Mexico offered, on behalf of his Government, to host the Third Consultation. Several other participants, however, stated that they were attending the Second Consultation as representatives of their Governments and were not in a capacity to make a commitment on behalf of those Governments, even though the Second Consultation had, in their view also, been most useful. Several more participants then supported the deletion of the qualifying phrase under discussion and the representative of Spain recalled that his Government had already addressed a letter to UNIDO offering to host the Third Consultation on the Pharmaceutical Industry. At the suggestion of one participant, it was finally agreed by consensus that the recommendations should refer only to "the Third Consultation".

66. Before closing the Consultation, the representative of Portugal, speaking on behalf of his Government, confirmed its commitment to the establishment of a research and development centre on pharmaceuticals in the interest of co-operation between developing countries. He added that his Government would continue its co-operation with UNIDO on that matter.

III. REPORT OF WORKING GROUP 1

Contractual arrangements for the transfer of technology

67. After a recapitulation by the secretariat of the issues, the Working Group agreed to the Chairman's proposal to discuss the issues in the order given in ID/WG.393/6, page 4. The Chairman suggested that in examining the three documents (ID/WG.393/1, 3 and 4) submitted to the Working Group for review and approval, only matters of major importance should be raised in order that the work could be completed by the Consultation.

68. Several participants pointed out that they should be free to suggest changes to the work of the Ad hoc Panel of Experts. The secretariat reminded participants that the documents as presented to the Working Group reflected more the views of the Ad Hoc Panel than those of the secretariat. Another participant recalled the consensus reached by the Ad Hoc Panel and urged that the agreed text should not be changed. Others who were members of the Ad Hoc Panel stressed the efforts undertaken in preparing the documents; although the texts might not have entirely incorporated their individual views on all aspects, they represented a reasonable compromise. It was also said that the texts as presented were well balanced and that delays in completing the work would not benefit anyone. It was then agreed that the documents would be carefully considered and suggestions would be passed on to the Ad Hoc Panel for its consideration in finalizing the document.

69. One participant pointed out that the term "contractual arrangements" used in ID/WG.393/6 should not imply that the documents were to be seen as model contracts. In that context, another participant said that no elements of a general nature should be included in those documents if they were under consideration at the United Nations Conference on a Code of Conduct for the Transfer of Technology negotiated under the auspices of United Nations Conference on Trade and Development.

70. Several participants stressed that the documents dealt only with the contractual arrangements for the 26 essential drugs contained in the UNIDO

illustrative list. It was to be seen as a guideline for specific cases. In that context, it was mentioned by several participants that technology for the production of those drugs was generally not patented; that should be kept in mind when referring to patents.

71. One participant stressed that the documents should not be considered as definitive or rigid; he suggested that one or two years after they had been disseminated an attempt should be made to evaluate their utilization with a view to revising them.

72. The problem of what one participant called the heterogeneity of developing countries as recipients of technology was discussed in the context of the applicability of the contractual documents. In connection with that, a participant stated that the aim was precisely to attempt to bridge those gaps, giving the developing countries guidelines.

73. One participant expressed regret that the consensus reached by the Ad Hoc Panel had not been maintained at the Consultation. In reply, several participants stressed that there had not been any controversy as to the quality of the work carried out by the experts of the Ad Hoc Panel, who had expressed themselves in their individual capacity, which might not necessarily reflect the opinions of their Governments and firms. Moreover, other representatives of Governments and interested parties were present at the Consultation and had the right to express their views. In the opinion of one participant the various comments and suggestions made on the three documents had not profoundly modified the original text.

74. Discussing what advice should be given to UNIDO on follow-up action, participants agreed that the documents presented constituted a valid basis for further work. There were, in the view of one participant, no similar guides available for the pharmaceutical sector to assist both Governments and the private enterprise in the developing countries to improve their information basis for negotiating agreements in the field.

75. Several participants stated that lack of practical knowledge on contractual arrangements had led many countries to conclude agreements that had proved too costly, did not stand the test of time, and could not be considered as mutually beneficial. As pointed out by some participants, developing countries needed impartial advice as provided by UNIDO through those documents. Another participant felt that, according to his experience, successful contracts were based on the good will of the parties and that the text of contracts was needed only in case of disputes; contracts were only a small fraction in implementing transfer of technology and no substitute for knowledge. The use of private consultants, as suggested by one participant, could not, in the view of several others, fill the information gap of many developing countries in that sector. Nor could they always provide the advice needed.

76. It was generally agreed that the documents should be disseminated to interested parties without delay; however, it was considered necessary to first review the documents in the light of all comments and suggestions made during the Consultation. The documents, as finalized by the Ad Hoc Panel, would be widely distributed. A few participants suggested that in cases of disagreement on the specific clauses, the various alternatives proposed by members of the Ad Hoc Panel should be presented and given equal weight.

77. As to the issue of completing the material presented in the three documents, participants generally agreed that there were a number of items not currently covered that deserved attention. The secretariat had suggested some points, e.g. use of competitive technologies, subcontracting, settlement of accounts and payments, notices and approvals, execution clauses. In that context, one participant expressed concern that that work would overlap with studies undertaken by United Nations Conference on Trade and Development as well as with the projected Code of Conduct on the Transfer of Technology. The secretariat replied that the studies of the United Nations Conference on Trade and Development secretariat essentially related to pharmaceutical policies, issues related to the use of generic versus brand names and pharmaceutical trade related aspects; as to the draft Code of Conduct, it was understood that UNIDO would translate the general principles contained in such a Code into practical arrangements for specific sectors. In that participant's view, UNIDO should also draw on the work undertaken by United Nations Commission on International Trade Law in the establishment of a legal guide on contracts for

the supply and construction of industrial works. The complementary material should, in the view of several participants, be reviewed by the Ad Hoc Panel and circulated as an expert report without awaiting review by a next consultation.

78. In the issue of preparation of documents on turn-key contractual arrangements and arrangements for technical assistance, one participant said that such work would provide developing countries with a useful complement to the three documents reviewed.

79. In the opinion of another participant, turn-key contracts should be well explained in terms of their advantages and disadvantages as they might not be suitable for all developing countries. Both closed turn-key contracts and unpackaged forms of contracts should be considered in the view of one participant as they corresponded to two different types of needs.

80. The specific suggestions and comments made by the Working Group to the Ad Hoc Panel on the three main documents presented to the Consultation are listed separately under the title of each document (see appendix).

Appendix to the report of Working Group 1

Suggestions made by participants at the Second Consultation to be communicated to the Ad Hoc Panel of Experts for their consideration in finalizing the three documents (ID/WG.393/1, 3 and 4) were as follows:

"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)

<u>Page</u>	<u>Para. or item</u>	<u>Suggested changes</u>
1	<u>Foreword</u>	Several participants suggested that the first sentence should be revised: (a) this document is the final version agreed to by the <u>Ad Hoc Panel of Experts</u> in their advice to UNIDO secretariat. or (b) the <u>Ad Hoc Panel</u> ...agreed to submit this document to the Second Consultation.
3	<u>Preface</u>	Several participants suggested including in the Preface a sentence stating that a contract should mean an agreement freely entered into by parties in accordance with the specific circumstances of each case and in keeping with national laws and regulations.

Another participant stressed that the very title of the document implied that there was no obligation to enter into contractual arrangements.

One participant opposed such inclusion as it might mislead the ultimate user of the document as to the applicability of national legislation that invariably constituted the frame for all contracts.

The secretariat pointed out the difficulties that would arise in trying to include a set of definitions in the documents. The secretariat also referred in that context to document ID/WG.393/17, paragraph 109, defining transfer of technology.

5 Last two
(i)

Correct punctuation.
Replace "likely" by "potential".

6 (iii)

Some participants suggested deletion of "particularly in developing countries" as the experience gained should refer to the developed countries.

Another participant suggested the wording be left as it was, or that reference be made to both developed and developing countries.

Other participants stressed the existence of a body of laws and practice on technology transfer agreements in developing countries that should be considered.

12 2.9

One participant suggested replacing "commercially proven" by "commercially feasible". That was opposed by several participants.

14 3.a.3

One participant suggested adding to that paragraph: "Often the value of know-how was of great economic importance sometimes equal to that of a patent". One participant was opposed to the inclusion of that text because of its implications in contractual relationships.

Another participant said that (a) unpatented did not mean unpatentable and (b) the value of know-how could go beyond the life of a patent.

One participant recalled that for the 26 drugs covered by the document, the patents had generally lapsed, and the know-how thereon was fully available.

- 19 3 and 4 A few participants suggested that these paragraphs might need reconsideration in the light of discussion on the subject of export restrictions mentioned on page 46.
- It was also suggested that a sentence be included to the effect that the licensor was also able to limit exports to countries where he produced the drugs concerned.
- One participant stated that several developing countries had national legislation that did not allow for export restriction clauses.
- 21 2 One participant suggested distinguishing between royalties paid for patent rights and royalties paid for know-how. In the first case, there should be no payment if the patent did not exist; payment should however continue if it were made for acquisition of know-how. The secretariat added that, if a patent application were rejected, there would not be grounds for payment as the technology was then in the public domain.
- 23 3 Patent immunity: It was suggested that the illustrative clause should reflect paragraph 4 on page 19.
- 24 6 One participant suggested a rewording of the last sentence: enforceable final ruling of a competent court.
- 31 1 Training: One participant indicated that the text should not be understood as implying obligation of results.
- 38 3.f.2 One participant suggested that the different positions of the United Nations Conference on a Code of Conduct on that issue be taken into account.
- The secretariat informed the Working Group that no agreement had so far been reached as to chapter 4 of the draft Code of Conduct, containing the reference mentioned, and that the Panel therefore could not rely on an agreed text.
- 42 (iii) Last sentence: the word "are" should be changed to "may be".
- 43 3.g.b One participant suggested that the different positions of the draft Code of Conduct on that issue should be taken into account.

- 45 3.g.6 Transfer of improvements: One participant stated that the paragraph seemed unbalanced as to the right of the licensee to have access to improvements.
- Other participants considered that the text was sufficiently balanced.
- 45 3.g.6 Another participant expressed the opinion that, during the lifetime of an agreement, the licensee had the right to obtain improvements developed by the licensor; if the licensor, however, had acquired such improvements from a third party, he should inform the licensee but could not be compelled to furnish the improvement.
- cont'd.
- The secretariat pointed out that there was no imbalance in the text as it reflected common business practice, notably as contained in the World Intellectual Property Organization licensing guide and the model contracts established by ORGALIME.
- Another participant stated that royalties also compensated for research and development costs; thus, the results of licensors' research and development had to be transmitted to the licensee.
- 47 1 One participant supported that the text should be reflected in the illustrative clauses given on page 48.
- 59 5.c.1 Scope (line 4): One participant suggested replacing the word "advisable" by "necessary".
- 60 5.c.2 One participant did not agree with the second sentence.
- 1st para.
- 61 5.c.1 Confidentiality: One participant suggested introducing into the first sentence the concept of "all information indicated by the licensor as being of a secret nature" or "trade secrets, secret know-how and all other confidential information".
- 61 5.c.3 One participant suggested an alternative clause (d) to the effect that confidentiality should be maintained until the information provided was no longer confidential.
- The secretariat noted that the issue of confidentiality was a controversial point in the Transfer of Technology Draft Code of United Nations Conference on Trade and Development and that it has been dealt with by some national legislations. The tendency was not to accept confidentiality without a time limit beyond the duration of the contract.

Another participant was opposed to the inclusion of the new suggested alternative and added that a normal time span would be five years.

Another participant said that his country's legislation would not permit unlimited confidentiality in transfer of technology agreements.

88 9.b. Term of the contract: Several participants
para. suggested that the reference to fixed time, i.e.
2 "five years", should be deleted. One participant said
that the time span was practised and should be
mentioned.

90/91 9.c. Several participants suggested that restrictions
on the use after expiration should be permitted in
the case of patented technology and secret know-how.
That should also be reflected in the illustrative
clauses. That issue was also dealt with in the draft
Code of Conduct.

90/91 9.c. On the above point the secretariat reminded partici-
pants that the basic objective of UNIDO was to
promote industrialization of developing countries
through transfer of technology for the production of
essential drugs. That did not imply negation of the
existence of patents and know-how. The above comments
also applied to other restrictive practices.

Such an exercise would be fruitless if it were to
restate and sanction restrictive practices that had
hindered transfer of technology, and that were
considered objectionable under many systems, as well
as in the draft Code of Conduct. Some participants
considered that the texts as they stood were
appropriate. One added that they were consistent with
the law of his country.

98 12.2 Sub-licensing: Some participants found the general
approach to the subject as stated in paragraph 2
unacceptable; one participant said that the text was
acceptable as it stood.

Another participant suggested mentioning the
alternative that sub-licensing was not possible.

Another participant said that sub-licensing only
occurred if it were agreed by both parties;
sub-licensing could also be to the benefit of the
licensor.

Several participants suggested that a reference
should be made to specific agreement by the licensor
to grant a sub-license.

98 In reply the secretariat referred to page 99, illustrative clause paragraph 2 (alternative a): mentioning the written consent of the licensor.

One participant suggested that the reference to "20 per cent" be deleted.

101 Applicable law: One participant suggested a more neutral wording, as in paragraph 2.a., of paragraph 1.a.

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

<u>Page</u>	<u>Para. or item</u>	<u>Suggested changes</u>
1	Foreword	See amendments suggested for ID/WG.393/1
3	Preface	See amendments suggested for ID/WG.393/1
3	3	One participant suggested that the coverage of the document could go beyond those drugs contained in the WHO model list. Another participant stated that the coverage should be restricted to the WHO model list. It was also suggested to add "among others" after "general application". General preference was expressed at keeping the wording as it was in the text.
3	3 line 2	One participant suggested deletion of "concrete" as it gave undue emphasis to the word "proposals".
4	1 (last line)	One participant suggested adding "...and should normally not contain...".
5	2	One participant suggested replacing the word "recommendations" by "statements and illustrative clauses provided in the document". Another participant suggested "general guidelines". In the view of other participants, the language used here should also be reflected in ID/WG.393/1.
5	(i)	See amendment suggested for ID/WG.393/1.
5	(iii)	See amendments suggested for ID/WG.393/1.
6	(3(c))	One participant questioned the term "life-saving". Another participant suggested replacing it by "health items".

- 6 3(b) and (c) One participant stated that it was unnecessary to refer to "sterile conditions" as that was generally known.
- Another participant said that as the document was primarily designed for the developing countries it was important to stage all requirements. That point was further agreed to by a participant who said that, in view of the high costs attached to quality control, Governments should be reminded of its importance.
- It was also stated that quality control should be independent of production.
- 7 A participant suggested that reference in the document to pharmacopoeias could only be indicative as account could not be taken of all of them. That also referred to the footnote on page 7.
- 7 3(d) Several participants requested that the three paragraphs on "generic products", "brand name products", "over the counter products" be rewritten by the Ad Hoc Panel.
- One participant disagreed with the content of that paragraph stating that there were also innovative companies that produced "generic products", and that brandnames were not allowed in some countries, including some industrialized ones.
- 7 3(d) Another participant referred to the issue of pharmacopoeial names, stating that there were several generic names for given products and that several (five main) pharmacopoeial descriptions existed.
- 9 4 One participant stated that the technology for formulation was not always to be seen as an easy activity; the absence of an obligation for continuous payments was often the case but not always. He suggested that a new paragraph be inserted after the first paragraph: "However, in a number of cases, continuous payments could be agreed upon: this would apply where galenic techniques techniques galéniques used contain some patentable specificities, or where their adaptation to a given case present difficulties or when this is so desired by the two parties in order to spread over time the payment of the formulation patent."

Another participant recalled that the issue had been discussed at length by the Ad Hoc Panel and that, despite the fact that there were indeed sometimes difficulties with the technology, there was no need to add further restrictions. The parties would have to decide on eventual payments. He suggested that the text be maintained.

A participant said that reference to "continuous payments" was not acceptable to him in view of his country's legislation on the matter.

A participant said that the last line of the first paragraph should read "...and should normally not contain restrictive conditions".

- 9 last para. One participant suggested adding the word "illustrative" (clauses).
- 12 1(a) One participant suggested adding "the Licensor is able and has the right to transfer".
- 14 2.1 One participant suggested deletion of "or legal assignee or successor" in both paragraphs 2.1 and 2.2.

The secretariat explained that the term had been added by the Ad Hoc Panel; the terms were used in a broad sense to mean beneficiary of assignment and legal successor.

- 14 2.6 (second line) One participant said that the term "marketing" was not defined. Another participant suggested replacing "marketing" by "sale".
- One participant said that the expression "raw materials" was inconsistent with the text on page 15 para. 29. Another one expressed that 2.6 should read "product's raw materials..."

- 14 2.7 One participant said that the licensor may not have all elements needed for registration. To another participant it seemed preferable to use "marketing authorization" instead of "registration". Another said that registration should be mentioned as a part of market authorization (which also included prices, etc.).

One participant said that the paragraph was addressed to local authorities in developing countries. In his view the paragraph should not be changed.

- 2.7 Licensor's information should not be restricted to that necessary for negotiation if in the recipient country there were requirements lower than in the Licensor's country.

Another participant suggested that it should be clarified whether the licensor had to generate all data required. He also said that post-registration medical work was not necessarily included; if it were registered, the licensee should absorb part of the relevant costs.

Several participants suggested maintaining the text.

One participant suggested adding to line 4 "... documents in possession of the licensor ...".

- 22 4(a) last line One participant noted that information must be kept secret if the contract remained without object.
- 23 1 (line 3) One participant suggested adding "in possession of licensor". The secretariat made reference in that context to p. 25, para. 4.1 and 4.2.
- 24 (c) One participant suggested that if a product were banned in one country it should no longer be used in an other.
- last 3 lines Another participant suggested that reference to developed or developing countries was not required as the rule should apply to all countries. One participant explained that if a product were banned for economic reasons in the licensor's country, the licensee could still use it; if, however, a product were banned for health reasons, it should also be banned in the licensee's country.
- 25 4.3 One participant suggested addition of "the licensee shall have reciprocal obligations to the licensor".
- 26 5 (third para.) One participant suggested including "transport costs".
- 29 6.3 (alt.b) One participant said that it was not clear who was responsible for the costs.
- 30 2 One participant suggested adding after */ "except in some particular cases such as galenic improvements" ("amélorations galéniques").
- 31 (b) Some participants disagreed with the content of that sentence. The secretariat explained that that was common use; if a patent was invalid, the licensee should not suffer the consequences. The draft Code of Conduct also contained similar formulations.

One participant said that para. 7.2, p.32 should be reflected in the commentary on p.31.

- 32 7.1 One participant suggested replacing "a license of use" by "a licence to make use and sell".
- 32 7.2(b) One participant indicated that the draft Code of Conduct referred to "disclosure" to the licensee and that a recent revision had added "...concerns in a direct matter...".
- 33 8 One participant suggested that reference be added to include the case that, if the contract were terminated for reasons attributable to the licensee, the licensor should obtain the transfer in his/her benefit of the licensee's trade-mark. The secretariat explained that that was not international practice and would correspond to a forced transfer without compensation.
- Another participant said the legislation of his country, for instance, would not allow retrocession or transfer of trade-marks; the licensor could only request the registration of another trade-mark. One participant said that he knew of no reference to such clause in international contracts.
- 33 third para. One participant said that the second sentence was too negative.
- 33 last para. One participant suggested two possible additions:
- (i) However, frequently the choice by the licensee of the licensor's trade-mark involves the latter in matters of quality and safety control of the product that would be beneficial to the public health of the country as well as for the licensee;
- (ii) If the contract provides for use of the product under a trade-mark in the name of the licensee, the licensor can reserve the right to approve the trade-mark chosen by the licensee; he can only oppose it for legitimate reasons.
- Those suggestions were intended to avoid negative implications that, for some participants, may be derived from the present text.
- 33 One participant indicated that the question of product liability should be developed in that context, particularly where the licensor's trade-mark was used and he was involved in quality control.
- 34 One participant suggested that illustrative clauses be drafted to cover a license of trade-marks by the licensor.

One participant suggested adding as an alternative illustrative clause:

"Alternative (b): The licensee will sell the product in the granted territory under the licensor's trade-mark."

- 35 5th para. One participant suggested adding: "Another is the case where the registration file contains a certain basic drug manufactured by a certain manufacturer. In such a case there are laws that prescribe the provision of this specific basic drug by this specific manufacturer."
- 35 6th para. He also suggested redrafting the first line as follows: "In any such situation the drugs should be...".
- 36 1 One participant suggested replacing the first five lines of the paragraph by the following: "The acquisition of basic drugs from the licensor itself or other source designated by it should not be imposed when not required to maintain the quality of the product when the supplier's trade-mark is used. Another possibility in ensuring the quality of products which bear a licensed trade-mark may be...".
- 36 1 That proposal should also be reflected, in accordance with the participant's opinion, in an illustrative clause.
- 39 10 (fourth para.) One participant suggested replacing that paragraph by the following: "In general, the acquiring party should not be required to transfer or grant back to the supplying party improvements arising from the acquired technology on an exclusive basis without offsetting consideration or reciprocal obligations from the supplying party."
- That should be reflected also in an illustrative clause.
- Another participant suggested adding at the end of the paragraph: "except if the secret of the main contract is jeopardized".
- 41 One participant said that exclusivity was a desirable goal in some cases, but that many of the developing countries did not have the basic infrastructure and the strength of their distribution network was not adequate; in such cases, it was preferable to have several licensees cover the health needs of the population.

One participant recalled that this item had been discussed by the Ad Hoc Panel and that it was quite unacceptable that the licensor would judge the adequacy or inadequacy of local systems. There was in addition, an issue of scale that made exclusivity a condition for a viable production. That view was supported by other participants.

One participant suggested that reference to "sole-licence" be included. Another participant, recalling the debate of the Ad Hoc Panel on Sub-licence, stated that that term should not be included.

42 11.1 One participant said that the term "item" was not defined; it should be replaced by "technical information" etc.

43 12 (first para.) One participant, disagreeing with that paragraph, suggested replacing it by the following:

"As mentioned before*/, technologies for formulations considered in this document are in the majority of cases well known and diffused. In a considerable number of cases, however, they do comprise secret information especially concerning stability of the product (including know-how of packaging) with special regard to tropical conditions.

43 "The technical information related to formulations may also include standard confidential information, e.g...." etc.

One participant said that the text did not require any change as it was based on a consensus achieved in the Ad Hoc Panel.

4 Another participant suggested adding: "In this case, a written undertaking by subcontractors and other third parties against disclosure may be advisable." That should also be reflected in the illustrative clauses.

One participant suggested adding that the subcontractor should be bound by a similar confidentiality as the licensee.

One participant referred to the confidentiality of medical and scientific information contained in dossiers presented for the registration of products. Another participant disagreed with their point as such information was often published and pertained to the public domain.

- 43 5 One participant proposed replacing "normally" by "exceptionally" and "exceptionally" by "normally". Another participant was opposed to those changes.
- 44 12.3 Same amendment as in document ID/WG.393/1
Altern. (page 61, 5.c.3).
(c)
- 47 3.1 One participant suggested that reference to "technical information" etc. conform with the definition of those terms.
- Altern. One participant suggested that the phrase read-
(a) ing "...the price of basic drugs... and in-
corporated in the products" be deleted.
- Another participant, referring to the over-pricing of raw materials, stressed that the clause should be maintained as it was.
- One participant suggested that the remuneration for engineering and other similar items not mentioned in paragraph 3.1 be included therein.
- 48 One participant said that in cases where the licensee used basic drugs different from those of the licensor's, the guarantees should not apply.
- 49 One participant suggested that the licensor should not provide guarantees or warranties if the licensee purchases bulk drugs or intermediates from sources other than the licensor or those not approved by him.
- 55 5th line One participant suggested changing "not very significant" to "may not be significant".
- 57 para. 2 One participant said that points 7 and 8 in his opinion were not RBPs.
- para. 3 A few participants suggested inserting: "...which unduly restrain competition and thereby have an adverse effect on the international transfer of technology."
- last para. One participant suggested deleting "most harmful".
- 58 para. 2 One participant suggested replacing "international" by "competitive".
- para. 3 One participant suggested adding in the first line "information that is not secret".

- last para. One participant suggested inserting: ...is "not"
line 3 agreed upon...
line 5 ..."and/or selling"...
- 5 One participant expressed that illustrative clauses should cover the three situations referred to in the paragraph. The secretariat reminded him that the objective of the exercise was neither to reflect extreme positions nor to incorporate in the text restrictive clauses that hindered the transfer of technology to developing countries, but to elaborate reasonable compromises for the parties. The participant who made the proposal conceded that complete prohibitions to exports should not be included, but considered existing alternatives not satisfactory.
- Another participant stated that the difference between "reasonable" and "unreasonable" restraints should be kept in mind; the objective was to eliminate "unreasonable" restraints. That was also currently being debated in the United States of America and European Economic Community.
- A participant recalled the consensus reached on the paragraph as it stood by the Ad Hoc Panel and suggested that the text be maintained. Another participant agreed.
- 62 para. 4 One participant suggested deleting "in principle".
- 66 last line One participant suggested adding "at its expense"
- 67 22.1 (alt.b) ..."and express written consent"
- 67 22.2 (alt.c) One participant suggested that subparagraph (iii) (iii) refer to the expense in connection with the training of sublicensee's personnel.
- 68 3rd para. One participant suggested replacing "allows" by line 2 "does not forbid" and referring to remarks made on applicable law in ID/WG.393/1.
- 69 He also suggested adding the paragraph to ID/WG.393/1.

"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)

<u>Page</u>	<u>Para. or item</u>	
L 2-5	Foreword Preface	Changes proposed for the foreword and preface of ID/WG.393/1 also apply.
13	3.1.1	One participant suggested adding: zoning and other permits.
25	7	One participant suggested including reference to the need to provide housing, office equipment, recreation etc. The secretariat pointed out that the subject was dealt with on page 18.
27	7.6 alternative (b)	One participant suggested deleting "official".
38	9.5	One participant suggested changing the word "divisible" for "confirmed".
57	15 (a) and (b)	One participant said that guarantees should also be given to the contractor as he would normally ask for them.
66	17.1	Second line from bottom: One participant suggested adding the word "proven" to the words "negligent act".
90	27	One participant referred to his suggestion as to a more neutral formulation as he had proposed to the section on "applicable law" in ID/WG.393/1.
92	28	Same suggestion as above referring to settlement of disputes. One participant proposed the inclusion of delivery terms. The secretariat pointed out that those were outside the purview of such contractual arrangements.
<u>Annexes</u>		One participant, noting the technical nature of the contents of the annexes, suggested that technical experts should check them. Another participant said that all annexes had been checked. The Chairman suggested that any further comments on these annexes, arising after examination by national experts, could be communicated to the <u>Ad Hoc</u> Panel through UNIDO.

IV. REPORT OF WORKING GROUP 2

Issue 2: Availability, pricing and transfer of technology
for bulk drugs and their intermediates

81. The Chairman requested the UNIDO secretariat to present the Progress Report (ID/WG.393/5) that summarized information on the issues based on a number of background documents. A representative of the secretariat explained that the Progress Report contained all the relevant facts on the issues, including the action taken on the recommendations of the First Consultation.

82. The Chairman then introduced issue 2 by presenting the corresponding background and issue papers (ID/WG.393/8 and ID/WG.393/9), and highlighting the three main points of discussions, namely, basic drug manufacture, formulation into dosage forms and national industrial drug policies.

83. In the discussion that followed, a number of countries presented an overview of their respective national pharmaceutical industry and experiences thereof.

Basic drug manufacture

84. Discussions centred on the pricing of imported bulk drugs and intermediates and on the transfer of technology for producing the drugs that were included in the UNIDO illustrative list of 26 essential bulk drugs.

85. Some participants regretted that it had not been possible to make progress on the issue of pricing. In the short run, they suggested that progress could be made by supplementing the UNIDO directory of reliable sources of supply with indicative or illustrative prices; they recognized the importance in the long run of the transfer of technology for the production of intermediates in developing countries.

86. A participant stressed that the domestic pricing of bulk drugs and pharmaceuticals depended directly on the pricing of raw materials and intermediates, which were often imported. Other participants indicated that the problem was not so much the price of intermediates and bulk drugs alone as

the non-availability of technology for producing many intermediates in developing countries; consequently not enough international competition existed to generate lower prices for those intermediates. One participant pointed to the role of the quality of technology and its management in that context.

87. A number of participants stressed their interest in offering technology to developing countries. However, some obstacles of a bureaucratic and fiscal nature of some inputs discouraged technology holders from offering that technology. It was pointed out that the size of the domestic market often determined the feasibility of the transfer of a particular technology, and that there was therefore a need to have several types of collaboration agreements, taking into account market size and conditions.

88. One participant pointed out that his offer to transfer the technology of one drug, which had been given to UNIDO earlier, had not been included in annex D of ID/WG.393/9. The secretariat stated that the annex included only information available from the survey of late 1982, and that his offer would now be transmitted to developing countries.

89. Some participants stressed that the aim of the transfer of technology should be to arrive at full integration from raw materials to bulk drugs to dosage forms. Hence, offers of technology that started from intermediates were insufficient because they did not solve the problems of pricing and of production of intermediates and bulk drugs in developing countries.

90. Many countries requested UNIDO to prepare a list of reliable technology holders willing to transfer their technologies to developing countries. They also requested that UNIDO carry out prefeasibility studies on the technologies offered and present technology alternatives to developing countries. A number of other participants indicated that before such prefeasibility studies could be undertaken several preliminary steps must be carried out such as analysis of health needs and drug requirements as well as the ways to satisfy those needs. A number of participants felt that many developing countries might not be able to produce drugs economically and that it might be to their benefit to continue to rely on imports of finished products.

91. Some participants said that some documents for the Second Consultation did not fully reflect the contents of the recommendations adopted by the Committee of Experts, in particular in paragraph 9 of its report (UNIDO/PC.59). The secretariat explained that the missing technical part had been incorporated into the questionnaire approved by that meeting, which was annexed to the background paper to issue 2 (ID/WG.393/9).

92. Other participants said that the questionnaire used in the survey carried out late in 1982 was too complicated and that the pharmaceutical industry found it difficult to complete. They suggested that a simplified questionnaire should be prepared in order to get a better response from the industry, making sure that the timing for sending out the questionnaire was appropriate. A representative of the secretariat explained that the questionnaire was prepared and approved by industry representatives attending the Committee of Experts and was considered suitable for the survey. Nevertheless, UNIDO would appreciate having a simplified questionnaire drawn up at the Second Consultation to obtain a better response from main technology holders.

93. Developing countries felt that, in view of the poor response from technology holders to the UNIDO survey of December 1982, UNIDO, on the basis of a simplified questionnaire, should carry out another survey in order to prepare a second list of interested technology holders. Meanwhile the prefeasibility studies referred to in paragraph 64 above should be undertaken with interested technology holders already identified by UNIDO. Some other participants offered UNIDO additional information on available technologies to produce bulk drugs and their intermediates for transfer to developing countries. One participant stated that he had received during the Consultation several requests as an immediate response to his announcement of the availability of 1 of the 9 priority drugs of the 26 included in the UNIDO illustrative list.

94. Some participants requested that a questionnaire to the Governments of developing countries should be prepared to ascertain their technology needs and specific drug requirements. Thereafter that information should be conveyed through UNIDO to technology holders for them to enter into bilateral negotiations.

95. In view of the difficulties in obtaining fully integrated technologies for the production of bulk drugs in developing countries, several participants proposed that UNIDO should set up a pharmaceutical technology assistance office to assess the surveys of drug technology and the appropriateness and price of such technologies. The financing of the office would be met partly by its users. One participant said that the proposal might be presented to the Industrial Development Board of UNIDO.

96. Another participant stated, however, that no criteria existed for determining the optimal technology, because it was in some cases protected by patents and confidentiality clauses and because it was always changing.

97. Some participants underlined the importance of strengthening South-South co-operation on pharmaceuticals so that developing countries could avoid repeating past mistakes when planning pharmaceutical production facilities. Many participants proposed the setting up of an industrial research and development pharmaceutical centre to support South-South efforts on that industry, and for which a feasibility study followed by an intergovernmental meeting of developing countries should be held. No financing for that centre from United Nations agencies was expected since the developing countries would endeavour to finance it themselves. A participant suggested that interested industrialized countries should be invited to join the centre. Several other participants considered the proposal for the centre premature. One participant suggested that the concept of the centre should be widened and take the form of a joint UNIDO-UNCTAD-WHO centre with broad terms of reference. Other participants proposed that UNIDO should cover the more promising areas for co-operation on pharmaceuticals in a world-wide study, which should also include transfer of technology.

Formulation into dosage forms

Directory of sources of supply

98. Participants found the "Directory of sources of supply of 26 essential bulk drugs, their chemical intermediates and some raw materials" (ID/WG.393/2) useful for diversifying the traditional sources of supply in developing countries.

Many participants also supported the extension of the coverage by the directory from the 26 essential drugs to all drugs included in the WHO model list of essential drugs and requested periodic updating of the UNIDO directory.

99. Some participants requested UNIDO to publish comprehensive information on all aspects of the pharmaceutical industry of importance to developing countries, either functioning as a clearing house for information or an information centre. In that way freedom of choice by developing countries would be preserved. Several participants requested that information on indication prices be given along with additional sources of supply.

100. A few participants were not convinced of the usefulness of an extended directory since there were other reference handbooks on world chemical drugs producers readily available. Those participants suggested that UNIDO should refer interested developing countries to sources of information such as existing handbooks rather than to sources of drug supply. Several participants were also against extending the coverage of the directory beyond the 26 essential drugs before the current directory had been made more accurate and complete.

Least developed of the developing countries

101. Some participants expressed willingness to promote South-South co-operation with the least developed of the developing countries on setting up formulation and packaging plants. One participant said that his country was willing to assist least developed countries and requested the UNIDO secretariat to provide him with a list of such countries that intended to establish pharmaceutical formulation plants.

102. Some participants stressed that for the least developed countries transfer of technology of bulk drugs did not solve their problem of accessibility to pharmaceuticals since their main problem was economic. However, they would need appropriate technology to formulate pharmaceutical bulk substances into dosage forms. One participant added that special attention should be paid to developing countries, notably chemotherapeutics against parasitic diseases for which there was no market in the developed countries.

103. A participant offered to transfer technology and provide technical assistance for the establishment of a pilot facility for producing infusions, injectables, vaccines and blood products. That facility would function on a regional basis.

National industrial drug policies

104. Some participants stressed that in the formulation of a national and industrial drug policy, priority should be given to the availability and quality of drugs as well as to their prices; such a policy would contribute to the improvement of health and to the development of the pharmaceutical industry. One participant considered that industrial drug policies was too ambitious a topic for discussion because of its political implications. Other participants considered the establishing of drug policies a difficult problem requiring lengthy national discussions, and counselled against discussing those topics.

105. Another participant supported the study of the technical aspects of national industrial drug policies, leaving political aspects to the discretion of Governments. Yet another participant stressed that in studying national industrial drug policies care should be taken to select countries of comparable levels of development or comparable aims for their corresponding drug policies.

106. Some participants requested that further case studies on industrial drug policies be carried out in order to provide information on comparative experiences. Those participants felt that such information could help developing countries to avoid repeating mistakes and to learn from the experience of others. A participant felt that no new case studies on national drug policies were needed since other United Nations organizations had already carried out such studies on many countries. Further, some participants expressed their opposition in general to UNIDO undertaking studies on industrial drug policies. Another participant reminded the Consultation of the role that WHO could play in helping developing countries to determine their health needs, especially in the areas of local production, quality control and manpower requirements and that WHO could also advise countries on their drugs needs and which of those drugs were suitable for local manufacture.

107. Some participants pointed to the linkage between UNIDO and WHO on national drug policies since industrial drug policies were subservient national health policies, and proposed that more case studies on the subject should be made. One participant suggested that UNIDO should study the relation between national drug policies and the development of the pharmaceutical industry.

108. An observer from WHO explained the background and aim of the WHO action programme on essential drugs and the main components of a national drug policy as defined by WHO. Among the latter, one of those components was the local production of drugs where it was economically and technically feasible. He further stressed the mandate of the Organization as the co-ordinating authority in world health work, with the aim of promoting required action on essential drugs. He pointed out that the action programme had been approved by the WHO Assembly in 1981. Another observer from WHO stated that within its mandate, both pharmaceuticals and biologicals should be safe, effective and made in accordance with WHO quality control standards and good manufacturing practices.

109. The observer from United Nations Conference on Trade and Development explained the background and the work of the United Nations Conference on Trade and Development in the field of transfer and development of technology, which included the formulation of strategies, plans and policies to accelerate the technological transformation of developing countries, and the establishment of appropriate institutional structures to implement them at the national, regional and international levels. Against this background, the observer described in detail the work programme of United Nations Conference on Trade and Development in the field of pharmaceuticals, which included policy-oriented studies and technology planning in the pharmaceutical sector. These studies have formed the basis for intergovernmental action and formulation of appropriate policies and institutional structures in the developing countries. They have constituted an important element of regional and international action on the subject.

Issue 3: The development of drugs based on medicinal plants

110. A representative of the secretariat presented issue 3 (ID/WG.393/10 and 11). The main points for discussion were the preparation of a data base for medicinal plants and the publication of a directory of medicinal plants, transfer of technology to produce known bulk drugs extracted from medicinal plants, and the preparation of guidelines to negotiate long-term supply of plant raw materials.

Data base and directory on medicinal plants

111. Many participants supported the establishment of a data base for medicinal plants and the publishing of a directory of medicinal plants. A participant stressed that the directory should help to compile national pharmacopoeias in developing countries. Another participant suggested that the directory be confined to medicinal plants of prospective economic value. Many participants suggested the collection and analysis of information on medicinal plants from available sources, including botanical, therapeutical and technological aspects.

112. Some participants suggested that medicinal plants be classified regionally when preparing the data base and the directory. Several participants requested that the data base be prepared in co-operation with all countries and that it should be accessible to every country. However, a participant stated that phytochemicals requiring sophisticated production technology need not be included in the directory; the data base should cover only those plants included in the WHO list of the most widely used medicinal plants.

113. A participant indicated that plant-based medicines were not always standardized and that knowledge was also lacking in developed countries.

114. The UNIDO secretariat stated that the plant species Papaver, Somniferum and Cannabis would not be considered in future UNIDO programmes in that field, since those were subject to the regulatory controls applicable under the jurisdiction of the International Narcotics Control Board.

Technology to produce plant-derived pharmaceuticals

115. Many participants stressed the need to acquire technology; a number of other participants offered technology to be transferred within a wider framework of co-operation between developed and developing countries and between developing countries themselves. The co-operation should cover the whole range of activities of the industry from crops to manufacturing to research and development. A participant, however, expressed that a distinction should be made between two groups of technologies for transfer to developing countries, namely, medicinal plants requiring simpler technologies and lower investment, and medicinal plants requiring complex technologies, high investments and large capacities. The former group was expected to have a wider application. Another participant stated that new technologies relevant to the processing of medicinal plants prevailing in developing countries should be developed in those countries.

116. A few participants suggested that crops be improved genetically from the viewpoint of phytochemical content, and that the exchange of seeds be facilitated between countries having seed banks.

117. A participant proposed the establishment of a United Nations inter-agency committee for the integral treatment of medicinal plants. Several other participants requested closer co-ordination of the activities of United Nations agencies in that field. It was also suggested that UNIDO set up a data bank to improve the transfer of technology for the processing of medicinal plants.

Guidelines for the negotiation of the supply of plant raw materials

118. Several participants felt the need for guidelines for the long-term supply of plant raw materials; several other participants considered that guidelines might not be necessary as that was a matter for bilateral negotiation. Another participant suggested that experts from developed countries should be consulted on the proposed actions on that topic.

Issue 4: The manufacture of vaccines in developing countries

119. Another representative of the secretariat explained issue 4 (ID/WG.393/12 and Rev.1; and 13 and Rev.1), and highlighted the main topics for discussion: a list of biological products for production in developing countries, steps required for an effective transfer of technology to manufacture classical and modern vaccines, and the domestic production of biologicals other than vaccines.

120. Many participants supported the proposals contained in the issue paper on the on the manufacture of vaccines in developing countries (ID/WG.393/12 and Rev.1). Those participants acknowledged the importance of quality control as even the imported quality vaccines were subject to deterioration during shipment and distribution. A participant felt that delays in procurement of certain vaccines crucial to specific regions could be overcome by regional manufacturing units. Another participant thought that the same solution was applicable to other biologicals that were difficult to get or were unavailable in the international market.

121. Many participants felt that there was no need to set up new production capacity for vaccines since there was ample world capacity to meet current and anticipated demand in the near future. Further, they suggested that developing countries should first establish national quality control facilities for biologicals and the necessary infrastructure for national

vaccination programmes. Finally, they suggested that in case Governments of developing countries desired to enter into domestic vaccine production, they should do so in a gradual way by stages, from the checking of imported vaccines to importing concentrated vaccines for blending, filling and packaging to producing domestic vaccines.

122. Several other participants, although supporting the views given in the above paragraph, expressed their readiness to transfer technology and offer training on a bilateral basis. One participant suggested that existing manufacturing facilities be evaluated and rehabilitated if needed before setting up new production units.

123. A number of participants in support of issues expressed their readiness to provide technology for a wide range of biologicals, such as human and veterinary vaccines and blood products, and also technologies for intravenous solutions and reconstituting fluids for vaccines with similar processes.

124. Many participants expressed the importance of co-ordination and collaboration with WHO and other United Nations agencies in that field.

Annex I

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Annex II

LIST OF DOCUMENTS

Issue papers

Issue 1

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

Items which could be included in licensing arrangements for the transfer of technology for the formulation of pharmaceutical dosage forms

ID/WG.393/3

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

Contractual arrangements for the production of drugs

ID/WG.393/6

Issue 2

Availability, pricing and transfer of technology for bulk drugs and their intermediates

ID/WG.393/8

Issue 3

The development of drugs based on medicinal plants

ID/WG.393/10

Issue 4

The manufacture of vaccines in developing countries

ID/WG.393/12
and Rev.1

Background documents

Progress Report	ID/WG.393/5 and Corr.1
Contractual arrangements for the production of drugs	ID/WG.393/7
Availability, pricing and transfer of technology for bulk drugs and their intermediates	ID/WG.393/9
The development of drugs based on medicinal plants	ID/WG.393/11
The manufacture of vaccines in developing countries	ID/WG.393/13 and Rev.1

Information documents

Directory of sources of supply of 26 essential drugs, their chemical intermediates and some raw materials	ID/WG.393/2
Technical profiles for production of pharmaceutical dosage forms	ID/WG.393/14 and Corr.1
The need for drug policies	ID/WG.393/15
Summary of the industrial property protection on pharmaceuticals in developing countries	ID/WG.393/16
Relevant topics to be taken into account in the preparatory phase of technology transfer arrange- ments for the production of pharmaceuticals	ID/WG.393/17
Multipurpose plant for production of UNIDO essential drugs based on raw materials and intermediates	ID/WG.393/18
Water use and effluent in the pharmaceutical industry	UNIDO/IS.388
Prospects for production of vaccines and other immunizing agents in developing countries	UNIDO/IS.402
Report of the Round Table Meeting on the Develop- ment of the Pharmaceutical Industry (Mohamedia, December 1981)	UNIDO/PC.33
Report of the Committee of Experts (Paris, October 1982)	UNIDO/PC.59
Report of the Meeting on Technical Cooperation among Developing Countries (Tunis, September 1983)	UNIDO/PC.76

