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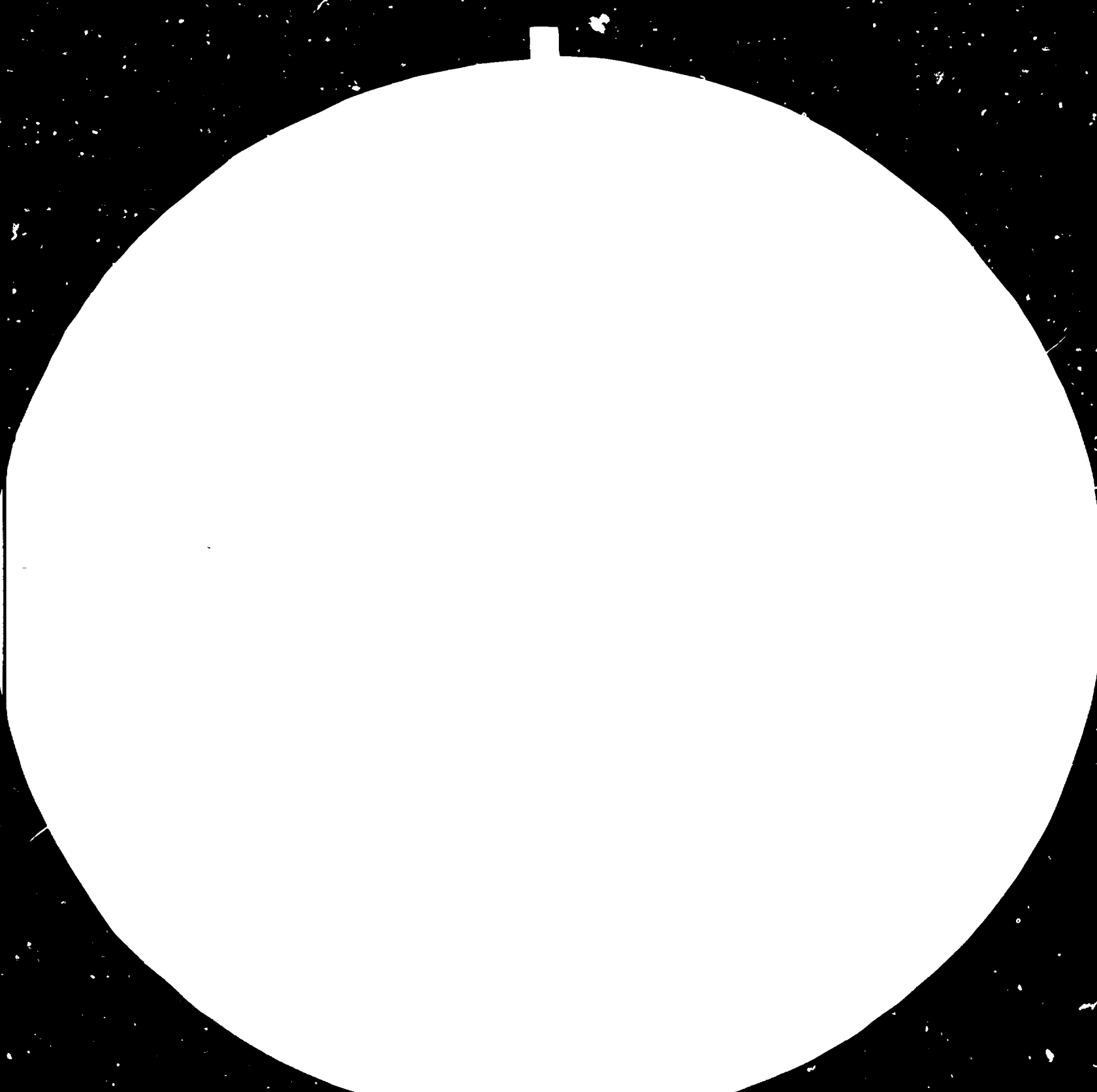

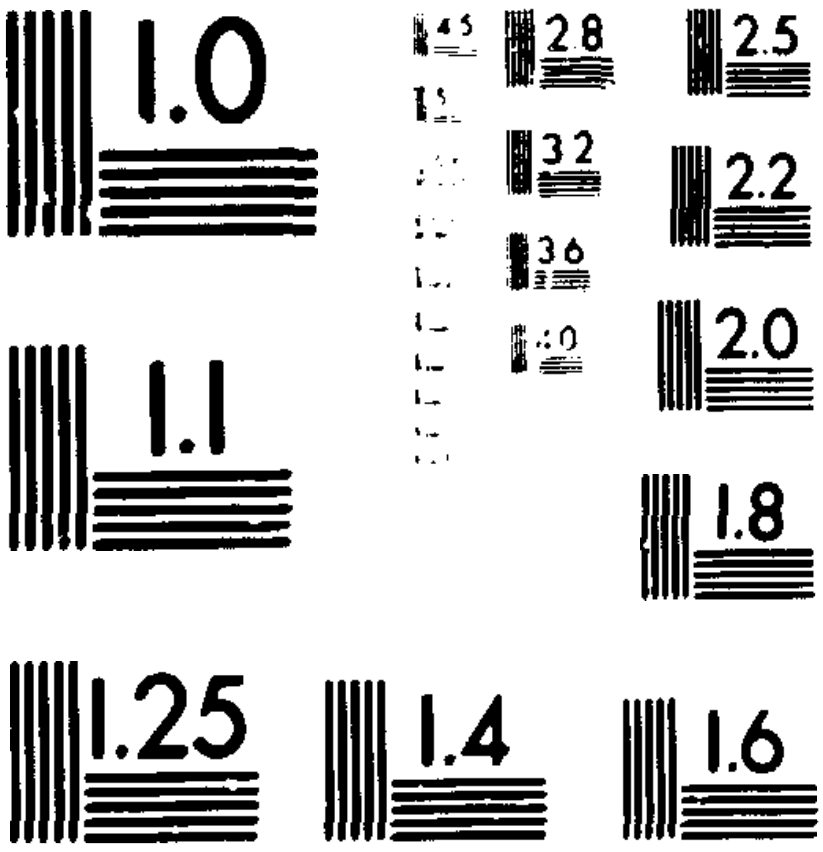

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UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

Meeting of the Advisory Panel
on Preventive Medicine
Vienna, Austria

27 - 28 February 1984

# REPORT *. (Meeting on preventive medicine)

2384

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CONTENTS



Appendix

# PREFACE

The Lima Declaration and Plan of Action on Industrial Development and Co-operation calls for the share of developing countries' total world industrial production to be increased to at least 25 per cent of the world manufacturing value added by the year 2000. The International Conference on Primary Health Care held at Alma Ata stressed the need for improving the health care facilities and economics of the health system of the developing countries.

The mandate of the United Nations Industrial Development Organisation (UNIDO) is to assist the developing countries in industrialisation. In fulfilling this mandate, UNIDO pays special attention to industry's contribution to meeting the basic needs of the population of the developing countries. One of the most important basic needs is the improvement of health care facilities.

UNIDO has already embarked on an extensive programme for the production of therapeutics. In the recent past, the need for assistance for the production of biologicals has acquired great urgency. It was considered that production of biologicals at national, regional and interregional level would ameliorate the health conditions and help in achieving relative self-reliance. The issue of local production in developing countries of biologicals was discussed at the Second Consultation on the Pharmaceutical Industry in November 1983 and specific recommendations on the matter were made by the participants.

UNIDO has established an Advisory Panel to advise on the techno-economic aspects of the establishment of UNIDO's programme of Industrial Production of Biologicals. The Panel will oversee and give advice on the implementation activities of the programme.

## I. ORGANISATION OF THE MEETING

### Opening of the Meeting

1. The meeting was opened by Dr. Abd-El Rahman Khane, Executive Director of UNIDO. In his inaugural address he explained the importance of UNIDO's programme in preventive medicine as a new field of technical assistance for the developing countries and the necessity of creating an Advisory Panel on Preventive Medicine providing substantial professional advice and guidance from high level representatives from both industry and government for the above programme.

The text of Dr. Khane's address is given in Annex 1.

### Election of Chairman

2. Dr. Charles Mérieux was unanimously elected as chairman.

Dr. Mérieux briefly addressed the members of the panel and thanked them for his election as Chairman and stressed the importance of the programme on Industrial Production of Biologicals (IPB), the need to create production capabilities for biologicals in the Third World and the need for co-operation among the members in order to successfully carry out the tasks assigned to the Panel.

3. Mr. L. Biritz, Deputy Director, Division of Industrial Operations, UNIDO, addressed the meeting and gave a general résumé of UNIDO and the activities of the Organisation, with regard to the industrialisation of developing countries.

4. Mr. Hacini, Deputy Director, Division of Policy Co-ordination, UNIDO also addressed the meeting. He elaborated upon the essential characteristics of the system of consultations and made reference to the two recent Consultations on the Pharmaceutical Industry held in December 1980 and in November 1981 in Lisbon and Budapest respectively. He went on to say how much these two consultations had assisted in understanding the problems facing the developing countries in the development of a local pharmaceutical industry. He outlined the objectives and task assigned to the Panel, that of guiding UNIDO to resolve the issues related to preventive medicine. He referred to WHO's considerable

progress in this field and he expressed the hope that UNIDO would receive useful assistance from WHO's experience in the implementation of UNIDO's programme on IPB.

The UNIDO Secretariat's presentation to the Advisory Panel

5. Ms. A. Tcheknavorian, Chief of the Pharmaceutical Industries Unit (Chemical Industries Branch/Division of Industrial Operations) and Chairperson of the Task Force on the Pharmaceutial Industry, UNIDO, presented a paper outlining the main principles and incentives of the IPB programme. In her speech she quoted the Director General of WHO, who stated in 1977 that UNIDO should be stimulated to take a greater interest in vaccine production in developing countries. She also highlighted the objectives and the methodology for implementation of the IPB programme. UNIDO intends to provide developing countries with all the relevant techno-economic information for establishing industrial production of biologicals. In this regard the main elements will be the assessment and choice of available technologies giving due importance to factors such as production strains, raw materials and equipment required; the quality, reproductibility and the cost of the product; the staff and infrastructure requirements; the minimum/maximum technical and economic scale of production and the investment required. The selected technology should be suitable for the recipient country depending on its level of development and capability to assimilate it. Consequently it is UNIDO's aim to collect and process information, to prepare directories of supply for raw materials, biologicals and even technologies and to prepare master plans as guidelines for developing production facilities.

The Agenda of the Meeting

6. The agenda was as follows: (i) opening of the meeting (ii) election of the Chairman (iii) brief presentation of IPB by the Secretariat, (iv) discussion on IPB and the draft Terms of Reference of the Advisory Panel (v) draft report of the meeting and (vi) date of the next meeting.

Documentation

7. The documents presented for the Advisory Panel are listed in Annex VII.

## II CONCLUSIONS AND RECOMMENDATIONS

8. The Panel recognised the objective of UNIDO to fill the vacuum which exists in fulfilling industrial production of biologicals in developing countries and recommended the establishment of the UNIDO programme for Industrial Production of Biologicals (IPB). It recommended that the terminology "conventional vaccines" be used for the programme instead of classical vaccines. The programme would include both conventional and some of the recently developed vaccines. However the short term programme would exclude some of the vaccines produced through modern biotechnological techniques.

9. The Panel adopted a list of priority biological products for the industrial production in developing countries as per Annex II.

10. The Panel adopted a questionnaire (Annex IV) for the preparation of a Directory of Sources of Technology for IPB in the context of transfer of technology.

11. The Panel agreed that the indicative list of non-confidential reference information required for assessment of Technology for the production of biologicals can be used for collection of information from the Public Sector in general and developing countries.

12. The Panel recommended that UNIDO with the advice of the members of the Panel should start preparation of a master plan for projects for industrial production of vaccines in developing countries which should include techno-economic details for the implementation of such projects at differ nt stages.

13. The Panel recommended the preparation of a study on the impact of modern technologies on production during the forthcoming decade of priority biologicals.

14. The Panel recommended that UNIDO and WHO should consider joint implementation of projects related to industrial scale production of human plasma fractions at regional and sub-regional levels. It also recommended holding a series of regional meetings in this context.

15. The Panel recommended that UNIDO collect up-to-date information on the modern technologies which deploy new techniques for the production of blood derivatives with a view to implementing projects in the foreseeable future.

16. The Panel recommended the preparation of a Directory of Producers for diagnostics which are used on a primary health care level and have priority in developing countries.

17. The Panel recommended the strengthening of co-operation in all aspects amongst UN agencies responsible for handling Biologicals in order to promote IPB. The co-operation should include establishment of joint programmes between UNIDO and UNICEF for the implementation of production units for conventional vaccines in developing countries.

18. The Panel recommended that its members should contact their Governments and explore the possibility of programmes for the production of biologicals in developing countries being established bilaterally or through the IPB programme of UNIDO.

19. The Panel recommended that any technology resulting in a particular biological product meeting the requirements of WHO should be transferred and should be available to all interested governments upon agreed terms.

20. The Panel recommended promotion of TCDC with specific reference to transfer of technology and advised the Secretariat to obtain data on available technologies.

21. The Panel recommended the establishment of IPB Fund. The contributions to this fund should be made by (i) UNIDO, through its industrial funding and (ii) through UNDP, World Bank and interested Governments and (iii) through UNICEF which is currently the major supplier of EPI vaccines to the developing countries.

22. The Panel recommended that as the manufacture of biologicals for veterinary use is included in UNIDO's long term programme FAO should be invited to become a member of the Advisory Panel.

## III SUMMARY OF THE DISCUSSIONS

23. The members of the Advisory Panel agreed with the Secretariat's presentation and approach to establish the programme on the Industrial Production of Biologicals (IPB). One member of the Panel referred to the necessity for the creation of the awareness that human life was of great value. Since it was felt that technical knowledge is more speedily accumulated than distributed he emphasised the need for sharing valuable knowledge and experience on an international level. Specifically the Panel agreed that developing countries should not have to depend solely on import and donation and therefore they should create the appropriate conditions for the reception of technologies for the production of biologicals. It was also agreed that some existing production facilities for veterinary vaccines in developing countries could be extended for the production of vaccines for human use.

24. Many members of the Panel expressed concern that developing countries were in need of information regarding biologicals for both human and veterinary use, a particular sub-sector of the Pharmaceutical Industry. It was agreed that providing information both on technological and economic aspects required for the establishment even of the nucleus of such an industry is of the utmost importance, since itis the prerequisite for any governmental decision of developing countries wishing to enter this field.

25. Another member emphasised that the production programme for biologicals cannot be prepared in a general manner since significant differences exist amongst developing countries regarding the availability of a technical infrastructure and skilled manpower. Hence the Second Consultation on the Pharmaceutical Industry recommended a step-by-step approach for the establishment of production capabilities for biologicals and the transfer of technology in stages, the Panel agreed that the starting stage for each interested developing country should be identified.

26. Another member suggested the establishment of a priority list of vaccines and proposed that UNIDO's IPB programme should be complementary to the EPI programme of WHO. After a lengthy discussion however it was agreed that in the IPB programme all types of biologicals could be included such as non-EPI and veterinary vaccines, modern biotechnological vaccines, blood products and diagnostics.

27. It was noted that different technologies are available for the manufacture of the same vaccine or other biological products which have an impact not only on the cost of the product but also on the adoption to the existing infrastructure of the recipient country. It was therefore emphasised that the identification of different sources of technology and their suitability to infrastructures at different levels would be another valuable step towards the development of the IPB programme in the Third World.

28. The quality control aspects of the IPB programme was highlighted in the discussion. It was noted that quality assurance was important in the production of safe and effective biologicals. The Panel noted that quality control of biologicals and in particular that of EPI vaccines is of major concern to WHO. It was also noted that WHO has already established quality control facilities for biologicals in all WHO regions.

It was also recognised that while the quality control is of utmost importance, production and quality control facilities for biologicals could simultaneously be developed in stages. Many members of the Panel stressed that there is no need to wait for the establishment of a quality control facility per se if desired to enter into the production of biologicals because quality control should obviously be included in the production programme. A quality control facility should be in place when production starts.

29. The cost-effectiveness of IPB programme was discussed at length. It was stated that the value of human life saved by such a programme cannot be assessed. The member from PAHO stated that while the cost per total immunising dose of the six EPI vaccines is US$ 0.52, the delivery system costs about US$ 4.5, therefore even an increase of 100% in the cost of vaccines would lead only to a 10% increase of immunization costs. However 10% overall increase of the costs of an immunization programme seems to be insignificant if it is compared with these values gained by the development of a production capability and a relative national self-sufficiency. The Panel therefore agreed that the developing of a production capability for vaccines to achieve a relative self-reliance could be envisaged even if cost comparisons would not allow the industry to make a start.

30. The representative from WHO made a statement to the Panel conveying in principle his support of the UNIDO programme on IPB. He also stated that

WHO is involved in an extensive programme of the development of vaccines, quality control and production. He proposed the use of the terminology of "conventional vaccines" instead of "classical vaccines" and stressed that priority should be accorded to the establishment of quality control before embarking upon a phased industrial production. The need was expressed by the WHO representative for making a distinction between transfer of technology and transfer of industrial technology. According to the Secretariat's view, such a distinction was not practical since developing countries have to start with the transfer of simple technologies for the creation of a nucleus which can then be scaled up at a later stage. It was also emphasised that plans for the implementation of the long-term objectives of the project should be prepared even if these would be achieved by a stage-wise approach. It was also noted that some facilities could be used for the production of human and veterinary vaccines.

Considerable discussion took place on the priority list of vaccines for production in developing countries. It was felt that the main focus should be on the EPI vaccines however it was recognised that non-EPI vaccines can be equally important for a different group of countries. Members agreed to the priority list of conventional vaccines which is appended as Annex II. This list was extracted from an illustrative list of biologicals prepared by the Secretariat (Annex III ). The illustrative list can also include the veterinary vaccines.

31. The issue of transfer of technology was discussed at length and an indicative list of non-confidential reference information required in this connexion prepared by UNIDO was discussed. Some members from the industry felt that this list is very detailed and many questions namely No. 4 to No. 9, cannot be answered by industry and technology holders. A sub-committee of the Panel was formed to redraft the list in order to have the maximum response from technology holders (Annex IV). However it was felt that the list presented by the Secretariat could be replied by public sector institutions as well as technology holders of developing countries. It was emphasised that quality control should be included in this list (Annex V ). In order to implement Technical Co-operation Among Developing Countries (TCDC) the members from the developing countries were requested to furnish the Secretariat with data on technologies available in developing countries for priority vaccines.

A member of the Panel offered to provide UNIDO with confidential/non-confidential information with regard to the production of priority conventional vaccines subject to clearance by his institution for the preparation of a master plan which could be used as a project concept and also for individual projects.

Several participants stressed that there are other potential sources of technology than the present vaccine suppliers to WHO and UNICEF. It was agreed that the first criterion in the assessment of the technology offered for transfer is the quality of the finished product. Only those technologies of biologicals should be recommended for transfer which result in finished products meeting the requirements of WHO.

32. With regard to modern biotechnological vaccines the Advisory Panel advised UNIDO to continue building up information reserves pertaining to all aspects for appropriate actions for phased adoption of the modern technologies when conditions are ripe for their implementation in developing countries. The members would assist UNIDO in having such information. A member of the Panel suggested the preparation of a study on the impact of modern technology on the production of priority biologicals during the forthcoming decade. Another member stressed however that UNIDO should also endeavour to obtain technology for biologicals manufactured by modern biotechnological techniques.

33. A member, while summarising the dicussion on the transfer of technology, highlighted three main criteria of its implementation namely (i) urgency i.e. the needs of the recipient country, (ii) timeliness i.e. appropriate conditions for reception of technology and (iii) prospects for success which includes adequate national support, availability of infrastructure and manpower and education for acceptance of technology.

34. Views were expressed about conducting of techno-economic feasibility studies for projects on production of vaccines. The Secretariat advised that extensive guidelines on this matter had been prepared by UNIDO and is available for the members of the Panel. The Panel emphasised that feasibility studies should be carried out, project by project and country by country for the production of vaccines in different stages.

35. The Panel agreed upon the importance of establishing facilities for plasma fractionation in developing countries. To fractionate human plasma several difficulties should be overcome such asquality control and collection of blood. It was noted that only 10% of the whole blood used for transfusion purposes was controlled with anti-D typing serum in an Asian developing country in 1982 because of the prohibitively high price of this diagnostic. The Secretariat suggested that the programme for plasma fractionation including collection of blood or placenta, fractionation or processing and quality control should be presented to developing countries in its administrative, technical,economical and social aspects. In this connexion the Chairman informed the Panel that the Government of France is collaborating with UNIDO in the organisation of a regional meeting on blood collection and fractionation in Cartagena, Colombia in November 1984, which could assist in the establishment of production capability for blood derivatives in Latin America on a regional/sub-regional level. The same exercise will be carried out in Asia in 1985 and in Africa in due course.

The members also highlighted the problems and difficulties associated with various aspects of the issue but they stressed the urgent need for action since blood products are not available in sufficient quality and quantity in developing countries. The member from PAHO informed the Panel that since 1979 blood donor centres have been established in Latin America which consequently could lead to developing capabilities for the fractionation of human plasma. A regional meeting at ministerial level in 1981 made the decision for the establishment of units for this purpose. The Panel stressed that a close collaboration between PAHO and UNIDO would be welcomed in the forthcoming meeting in Cartagena.

36. A member highlighted the necessity of not losing sight of the developments of new recombitant DNA technologies in production of plasma fractions. The Secretariat appreciated the concern and expressed the difficulties it faces in securing such technologies and invited the Panel to advise UNIDO on the matter. The Secretariat stressed that developing countries should develop capabilities to adopt proper technologies resulting in quality products and acceptable costs such as blood derivatives from placenta or insulin from pancreas. The representatives of WHO once again stressed the importance of specific requirements in all phases of collection, fractionation and quality control of blood products.

37. A member from a developing country emphasised the importance of diagnostics in the health care programmes. The representative from WHO agreed to provide a list of priority diagnostic reagents included in WHO's programme on rapid diagnostics. UNIDO's contribution in the area of diagnostics should also be to promote the local manufacture of plastic containers and test plates which are required for the performance of tests. The representative from WHO remarked that the quality of the plastic used is very important. The members of the Panel stressed the importance of collecting information on diagnostics and requested the Secretariat to make its best endeavour to prepare a Directory. The Secretariat agreed to prepare a directory of producers of diagnostics and also those of plastic consumables.

38. A member from a developing country emphasised the importance of establishment of direct contact between UNICEF and UNIDO. Since UNICEF has a major role in procuring and supplying vaccines to developing countries and also for raising funds for implementing projects in its GOBI programme, UNICEF and UNIDO may jointly implement projects in the IPB programme. The importance of bilateral and multilateral co-operation was also stressed. UNIDO requested members of the Panel to contact their Governments and explore the possibility of programmes for the production of biologicals to be established bilaterally or through the IPB programme of UNIDO.

39. The Panel noted the conclusions and recommendations of the Second Consultation on the Pharmaceutical Industry and it was agreed that from the dicussions which took place in the meeting, adequate guidance was available for implementation of the recommendations. It was also noted that the recommendation of the Second Consultation pertaining mainly to scorpion anti-venom could not be discussed, due to shortage of time. The topic could be discussed at the next meeting of the Panel.

40. The Panel expressed considerable concern with regard to the availability of sources of finance for the implementation of the IPB programme since the success of this programme depended on having its own resources. After considerable discussion, the Panel recommended the establishment of an IPB fund. It was recommended that contributions to this fund should come firstly from UNIDO through its industrial funding and this part of the fund be used for preparation of the IPB. Secondly contributions should be secured from UNDP, the World Bank and interested Governments and this part of the fund be used for carrying out feasibility studies of industrial projects in developing countries. Thirdly it was recognised that UNICEF could assist directly in the case of fund raising activities for the implementation of the projects. The member from UNICEF agreed in principle to this concept. The Secretariat welcomed the idea that UNIDO could receive assistance from the existing fund raising system of UNICEF for the implementation of projects for biologicals.

41. The Panel very briefly discussed the draft Terms of Reference of the Advisory Panel on Preventive Medicine.

42. The Panel agreed that the next meeting will be held in Cartagena, Colombia in November 1984.

ANNEX 1

Excellencies, Dear Colleagues,

Ladies and Gentlemen,

I wish to extend a most heartfelt welcome to all of you. May I start by recalling that the United Nations Industrial Development Organization's mandate is to assist in the industrialization of developing countries. Although the main line of our action is in response to requests from our Member States, we nevertheless consider as part of UNIDO's mandate giving special attention to industry's contribution in meeting the basic needs of the population of the Third World. One of the most crucial basic needs is the improvement of health care facilities for all the people of the world. Following the 1978 Alma Ata Declaration the Industrial Development Board of UNIDO decided to give prominence to the activities of UNIDO in the field of the pharmaceutical industry in the developing countries, particularly as this industry is considered by many developing countries to be a strategic area of development.

The developed countries have made remarkable progress in medical care provided to their populations, including diagnosis, preventive and curative treatment. This is far from being the case in the Third World. Approximately 10 per cent of the over 100 million children born each year in the developing countries die before they reach their first birthday. It is reported that in 1983 simple curable diarrhoreal disease took a death toll of between 5 and 6 million lives. Some further 5 million children died from vaccine preventable diseases. This works out at approximately 1 child every three seconds. An equal number was blinded, crippled or left with mental retardation mainly because of measles, polio or whooping cough.*

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* D. Taylor, The chance of a lifetime, World Health, September 1983

It costs approximately US $ 5 to fully immunize a child** which is more than the overall per capita allocation for health in many developing countries which therefore can hardly afford the above mentioned costs of immunization.*** This is the main reason why the coverage of immunization is less than 30% in the developing countries.

For many years WHO and UNICEF have been making a great effort to resolve this situation with global programmes such as the Expanded Programme on Immunization (EPI), the Global Quality Assurance Certification Scheme, the Action Programme of Essential Drugs and Vaccines together with the Programme for Control of Diarrhoreal Diseases. UNICEF has initiated the UNICEF GOBI-FFF programme which stands for the simple and low cost methods of growth monitoring, oral rehydration therapy, breast feeding, immunization and others. All these global programmes are aimed at successful implementation of Health for All by the year 2000.

UNIDO is joining in these efforts and assistance is provided in the industrial aspects of preventive medicine. In recent years an increased number of requests have been received from developing countries for Technical Assistance, particularly with regard to the manufacture of vaccines and blood products from amongst biologicals. The developing countries have expressed to UNIDO the necessity of following up the efforts by which the targets of EPI are being achieved. One of the solutions whereby the governments of developing countries could maintain the achievements of EPI at a high level, is by means of an industrial approach. With an industrial approach the developing countries have the opportunity of developing their own capability and thereby reaching a level of relative self-reliance in the manufacture of the most important vaccines. This is why UNIDO has also

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** 1984 EPI Revolving Fund Prices, EPI Newsletter Vol. V No. 6 1983
*** Primary Health Care: A First Assessment, World Health, September 1983

decided to submit for consideration to the Second Consultation on the Pharmaceutical Industry, held in Budapest, Hungary in November 1983, a new issue relating to the production of vaccines in the developing countries. As you know the Consultation agreed that the manufacture of vaccines differs significantly from other pharmaceutical products, and that the transfer of technology could be offered in stages. The vaccines thus produced should be entirely in compliance with WHO requirements.

By implementing projects in this field at different techno-economic levels, UNIDO intends to create a programme on the industrial production of biologicals (IPB) and wishes to provide concepts of industrial projects for those developing countries where enough awareness and sensitivity towards the importance of the preventive side of public health, has been developed.

In order to build up and implement such a programme, UNIDO would welcome the sustained professional advice and guidance of high level representatives from both industry and governments. For these purposes, I have decided to establish in UNIDO an Advisory Panel on Preventive Medicine.

I would like to express my appreciation of your kind acceptance of my invitation to become members of this Advisory Panel and I also greatly appreciate the presence of our distinguished colleagues from WHO, PAHO and UNICEF. I am convinced that your professional expertise and experience will guide UNIDO to successfully contribute through its IPB programme to the attaining of the WHO proclaimed objective: Health for all by the year 2000.

Finally I would like to wish you every success in this first meeting and I trust that we shall meet here several times in the coming years, when we may analyse and evaluate the results of this programme.

Thank you.

## ANNEX II

## PRIORITY LIST OF VACCINES FOR HUMAN USE FOR PRODUCTION IN DEVELOPING COUNTRIES

### A. Conventional Vaccines

#### I. Vaccines recommended for use in the EPI

BCG

DPT

Diphtheria-tetanus vaccine

Live measles vaccine

Oral poliomyelitis vaccine

Tetanus vaccine

#### II. Non-EPI vaccines

Rabies vaccine produced in cell cultures

Poliomyelitis vaccine for parenteral use

Yellow fever vaccine

Japanese encephalitis vaccine

## ANNEX III

## ILLUSTRATIVE LIST OF BIOLOGICALS FOR INDUSTRIAL PRODUCTION IN DEVELOPING COUNTRIES

### A. Conventional Vaccines

#### I. Vaccines recommended for use in the EPI

BCG

DPT

Diphtheria-tetanus vaccine

Live measles vaccine

Oral poliomyelitis vaccine

Tetanus vaccine

#### II. Non-EPI vaccines

Rabies vaccine produced in cell cultures

Poliomyelitis vaccine for parenteral use

Yellow fever vaccine

Japanese encephalitis vaccine

Anti-leprosy vaccine

### B. Modern Biotechnological Vaccines

Hepatitis B, A and non A non B

Anti-malaria vaccine

### C. Blood Products

#### I. Plasma fractions (human)

Albumin

Anti-haemophilic fractions

#### II. Sera and immunoglobulins

Anti-D immunoglobulin

Anti-rabies hyperimmune serum

Anti-venom sera

Tetanus antitoxin

ANNEX IV

# QUESTIONNAIRE

## Directory of Sources of Technology for IPB

1. In principle, are you interested in transfer of technology (TOT)?

   Yes ☐

   No ☐

2. If yes, please check the box of the product for which you can transfer technology;

   2.1 BCG vaccine (dried) ☐

   2.2 Diphtheria-pertussis-tetanus vaccine ☐

   2.3 Diphtheria-tetanus vaccine ☐

   2.4 Live Measles vaccine ☐

   2.5 Oral Poliomyelitis vaccine ☐

   2.6 Tetanus vaccine ☐

   2.11 Rabies vaccine produced in cell cultures ☐

   2.12 Poliomyelitis vaccine for parenteral use ☐

   2.13 Yellow fever vaccine ☐

   2.14 Japanese encephalitis vaccine ☐

3. Please specify the following data of the products for which technology can be transferred.

3.1 BCG vaccine (dried)

(i) Production strain _____

(ii) Production presentation _____

_____

(iii) Production method: fermenter ☐

static culture ☐

(iv) Does the product meet the WHO requirements?

Yes ☐

No ☐

(v) Number of countries in which the product is licensed for sale:

own country only ☐

1 to 5 ☐

6 to 10 ☐

11 to 15 ☐

more than 15 ☐

3.2 Diphtheria-pertussis-tetanus vaccine

(i) Production strain _____

(ii) Product presentation _____

_____

(iii) Production method: fermenter ☐

static culture ☐

(iv) Does the product meet the WHO requirements?

Yes ☐

No ☐

(v) Number of countries in which the product is licensed for sale:

own country only ☐

1 to 5 ☐

6 to 10 ☐

11 to 15 ☐

more than 15 ☐

3.3 Diphtheria-tetanus vaccine

(i) Production strain _____

(ii) Product presentation _____

_____

_____

(iii) Production method:

fermenter ☐

static culture ☐

(iv) Does the product meet the WHO requirements?

Yes ☐

No ☐

(v) Number of countries in which the product is licensed for sale:

own country only ☐

1 to 5 ☐

6 to 10 ☐

11 to 15 ☐

more than 15 ☐

3.4 Live Measles vaccine

(i) Production strain _____

(ii) Product presentation _____

_____

_____

(iii) Production method:

fermenter ☐

static culture ☐

(iv) Does the product meet the WHO requirements?

Yes ☐

No ☐

(v) Number of countries in which the product is licensed for sale:

own country only ☐

1 to 5 ☐

6 to 10 ☐

11 to 15 ☐

more than 15 ☐

3.5 Oral Poliomyelitis vaccine

(i) Production strain _____

(ii) Production presentation _____

_____

(iii) Production method:

fermenter ☐

static culture ☐

(iv) Does the product meet the WHO requirements?

Yes ☐

No ☐

(v) Number of countries in which the product is licensed for sale:

own country only ☐

1 to 5 ☐

6 to 10 ☐

11 to 15 ☐

more than 15 ☐

3.6 Tetanus vaccine

(i) Production strain _____

(ii) Product presentation _____

_____

(iii) Production method:

fermenter ☐

static culture ☐

(iv) Does the product meet the WHO requirements?

Yes ☐

No ☐

(v) Number of countries in which the product is licensed for sale:

own country only ☐

1 to 5 ☐

6 to 10 ☐

11 to 15 ☐

more than 15 ☐

3.11 Rabies vaccine produced in cell cultures

(i) Production strain _____

(ii) Product presentation _____

_____

_____

(iii) Production method:

fermenter ☐

static culture ☐

(iv) Does the product meet the WHO requirements?

Yes ☐

No ☐

(v) Number of countries in which the product is licensed for sale:

own country only ☐

1 to 5 ☐

6 to 10 ☐

11 to 15 ☐

more than 15 ☐

3.12 Poliomyelitis vaccine for parenteral use

(i) Production strain _____

(ii) Product presentation _____

_____

_____

(iii) Production method:

fermenter ☐

static culture ☐

(iv) Does the product meet the WHO requirements?

Yes ☐

No ☐

(v) Number of countries in which the product is licensed for sale:

own country only ☐

1 to 5 ☐

6 to 10 ☐

11 to 15 ☐

more than 15 ☐

3.13 Yellow fever vaccine

(i) Production strain _____

(ii) Product presentation _____

_____

_____

(iii) Production method:

fermenter ☐

static culture ☐

(iv) Does the product meet the WHO requirements?

Yes ☐

No ☐

(v) Number of countries in which the product is licensed for sale

own country only ☐

1 to 5 ☐

6 to 10 ☐

11 to 15 ☐

more than 15 ☐

3.14 Japanese encephalitis vaccine

(i) Production strain _____

(ii) Product presentation _____

_____

_____

(iii) Production method:

fermenter ☐

static culture ☐

(iv) Does the product meet the WHO requirements?

Yes ☐

No ☐

(v) Number of countries in which the product is licensed for sale

own country only ☐

1 to 5 ☐

6 to 10 ☐

11 to 15 ☐

more than 15 ☐

4. Do you have experience in transfer of technology to developing countries?

Yes ☐

No ☐

5. If yes, please indicate the number of countries to which you have successfully transferred technology:

1 to 5 ☐

6 to 10 ☐

11 to 15 ☐

more than 15 ☐

6. Please indicate the forms of technology transfer which you are willing to consider:

(a) Turn-key project ☐

(b) Licensing ☐

(c) Joint venture ☐

7. If you have crossed 6(a) or 6(b), for how long are you willing to provide technical/development assistance?

1 year ☐

1 to 5 years ☐

5 to 10 years ☐

more than 10 years ☐

8. Would you be ready/able to provide bulk vaccine for local filling during the period of TOT?

Yes ☐

No ☐

9. Would you be ready/able to provide training in your

| | Yes | No |
|---|---|---|
| pilot plant premises? | ☐ | ☐ |
| commercial plant premises? | ☐ | ☐ |

10. Would you be ready/able to assist in the establishment of

| | Yes | No |
|---|---|---|
| in-process control laboratory? | ☐ | ☐ |
| quality control facilities? | ☐ | ☐ |

11. Do you conduct regular R and D activities on

| | Yes | No |
|---|---|---|
| bulk vaccine | ☐ | ☐ |
| dosage form | ☐ | ☐ |

to improve production technologies?

Date _____

Respondent's name: _____

Address : _____

_____

Phone : _____

## ANNEX V

### INDICATIVE LIST OF NON-CONFIDENTIAL REFERENCE INFORMATION REQUIRED FOR ASSESSMENT OF INDUSTRIAL TECHNOLOGY OF BIOLOGICALS

1. Name of product
2. Availability of product
3. Production flow-chart, non-confidential
4. Yield of phase product
5. Reproductibility of production concerning yield, purity and potency of phase product
6. Informative prices of direct material costs
7. Total conversion costs (utilities, energy, salaries and wages, depreciation, maintenance, overheads)
8. Fixed capital requirements for investment and estimated percentage of hard currency required
9. Minimum technical and minimum economic scale
10. Quality Control(tests performed and estimated costs)
11. Environmental considerations
12. Labour safety regulations
13. Special factors affecting present process economics, non-confidential
14. Infrastructure required
15. Skilled personnel required
16. Type of technology transfer (licensing, joint-venture etc.)
17. Availability of supply of technology
18. Extent to which the technology supplier is willing to provide assistance and support of different types of technology transfer
19. Any other relevant non-confidential reference information

ANNEX VI

## LIST OF PARTICIPANTS

### MEMBERS OF THE ADVISORY PANEL

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UNITED STATES OF AMERICA

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(Representative of Pharmaceutical Manufacturers Association, USA)

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Mr. Roger Goodall
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DELEGATES FROM THE WORLD HEALTH ORGANISATION

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WHO, Geneva, Switzerland

Dr. F.T. Perkins,
Chief,
Biologicals,
WHO, Geneva, Switzerland

MEXICO*

Lic. Mauricio Maria y Campos
Sub-Secretario
Ministerio de Industria
Mexico City, Mexico

* Member unable to attend First Meeting of the Panel

ANNEX VII

LIST OF DOCUMENTS

1. Programme for the Industrial Production of Biologicals (IPB), Brief presentation by the UNIDO Secretariat to the Advisory Panel on Preventive Medicine, Vienna, 27 February 1984.

2. UNIDO Programme for Industrial Production of Biologicals (IPB), An Introductory Paper, Vienna 27 - 28 February 1984.

3. Second Consultation on the Pharmaceutical Industry, Budapest, Hungary 21 - 25 November 1983, Report, UNIDO/ID/311.

4. The Manufacture of Vaccines in developing countries, Issue Paper, UNIDO/ID/WG.393/12/Rev. 1.

5. The Manufacture of Vaccines in developing countries, Background Paper, UNIDO/ID/WG.393/13/Rev. 1.

6. Prospects for the Production of Vaccines and Other Immunizing Agents in developing countries, UNIDO/IS.402.