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UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

THIRD CONSULTATION ON THE PHARMACEUTICAL INDUSTRY

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REPORT

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PREFACE

The Second General Conference of the United Nations Industrial Development Organization (UNIDO), held at Lima, Peru, in March 1975, recommended in paragraph 66 of the Lima Declaration and Plan of Action on Industrial Development and Co-operation 1/ that UNIDO should include among its activities a system of continuing consultations between developed and developing countries, with the object of raising the developing countries' share in world industrial output through increased international co-operation. 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.

At its fourteenth session, in May 1980, the Industrial Development Board decided to establish the System of Consultations on a permanent basis. 2/ At its sixteenth session, in May 1982, the Board adopted the rules of procedure, 3/ according to which the System of Consultations was to operate, together with its principles, objectives and characteristics (ID/B/258, annex). Notably:

The System of Consultations shall be an instrument through which UNIDO is to serve as a forum for developed and developing countries in their contacts and consultations directed towards the industrialization of developing countries;

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

Participants of each member country should include representatives of Governments, industry, labour, consumer groups and others, as deemed appropriate by each Government;

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

1/ See Report of the Second General Conference of the United Nations Industrial Development Organization (ID/CONF.3/31), chap. IV.

2/ Report of the Industrial Development Board on its fourteenth session (Official Records of the General Assembly, Thirty-fifth Session, Supplement No. 16 (A/35/16)), vol. II, chap. XI, para. 153.

3/ Report of the Industrial Development Board on its sixteenth session (Official Records of the General Assembly, Thirty-seventh Session, Supplement No. 16 (A/37/16)), chap. IV, para. 46.

Two Consultations have been convened on the pharmaceutical industry. The First Consultation on the Pharmaceutical Industry was held at Lisbon, Portugal, from 1 to 5 December 1980. 4/ The Second Consultation on the Pharmaceutical Industry was held at Budapest, Hungary, from 21 to 25 November 1983. 5/ The Industrial Development Board of UNIDO, at its nineteenth session, held in May 1985, decided that a third Consultation should be held during the biennium 1986-1987. 6/

Thirty-one Consultations have been convened since 1977, covering the following industries and topics: capital goods, agricultural machinery, iron and steel, fertilizers, petrochemicals, pharmaceuticals, leather and leather products, vegetable oils and fats, food-processing, industrial financing, training of industrial manpower, wood and wood products, building materials and fisheries.

4/ Report of the First Consultation on the Pharmaceutical Industry, Lisbon, Portugal, 1-5 December 1980 (ID/259).

5/ Report of the Second Consultation on the Pharmaceutical Industry, Budapest, Hungary, 21-25 November 1983 (ID/311).

6/ Report of the Industrial Development Board on the work of its nineteenth session (Official Records of the General Assembly, Fortieth Session, Supplement No. 16) (A/40/16), para. 89(3).

CONTENTS

INTRODUCTION

1. The Third Consultation on the Pharmaceutical Industry was held at Madrid, Spain, from 5 to 9 October 1987. The Third Consultation was attended by 286 participants from 61 countries and 14 international and other organizations (see annex I) and was held at the invitation of the Government of Spain.

Background to the Third Consultation

2. UNIDO organized two Consultations on the pharmaceutical industry, in 1980 and 1983, at which participants emphasized the importance of developing domestic pharmaceutical production in developing countries, covering all the major subsectors related to both preventive and curative medicine, including the production of pharmaceutial chemicals and their intermediates. They took into account factors involving policy and production measures and identified a number of issues involved in the promotion and development of the industry in developing countries.

3. In response to the recommendations of the First Consultation, UNIDO convened a round-table meeting of experts in December 1981, a committee of experts on pharmaceuticals in October 1982 and an ad hoc panel of experts on contractual arrangements in December 1982 and April 1983, as well as a meeting on co-operation among developing countries in September 1983. UNIDO simultaneously undertook a study of technical, economic and environmental aspects related to the transfer of technology and the development of the pharmaceutical industry.

4. As a follow-up to the recommendations of the Second Consultation, UNIDO convened a third meeting of the ad hoc panel on contractual arrangements, and the panel gave their final views regarding three documents on contractual arrangements for the production of drugs (pharmaceutical chemicals, their intermediates and pharmaceutical formulations). With regard to the availability, pricing and transfer of technology for pharmaceutical chemicals and their intermediates, UNIDO prepared a number of studies and carried out surveys on sources of supply for pharmaceutical chemicals and intermediates and on the availability of technology. It also endeavoured to put technology recipients in contact with the technology holders, provided technical assistance and conducted feasibility studies leading to the integrated development of the pharmaceutical industry and transfer of technology for the production of pharmaceutical chemicals.

5. In February 1985, UNIDO convened an informal meeting of experts on medicinal plants, as a result of which UNIDO: (a) collected information on five medicinal plants of known therapeutic importance, including botanical, ethnomedical, chemical, pharmacological, agro-technological, technology and market aspects; (b) prepared guidelines to improve the supply of medicinal plants as raw materials or processed products, in addition to documents on the transfer of technology for the genetical improvement of medicinal plants; and (c) intensified its technical assistance programme.

6. UNIDO established an Advisory Panel on Preventive Medicine to implement a programme on the industrial production of biologicals, which met four times since the Second Consultation. On the recommendation of the Panel, a sub-account of the United Nations Industrial Development Fund was established to finance the implementation of the programme. UNIDO also prepared a

document on techno-economic aspects of the industrial production of biologicals, assisted in the establishment of a pilot demonstration unit for vaccine production, responded to requests for the rehabilitation or expansion of existing production and control facilities in Africa and held discussions with United Nations agencies and bilateral aid organizations on the need for assured utilization of domestically manufactured biologicals. UNIDO also convened meetings at the regional level in 1984 (Latin America) and 1986 (Asia).

7. In addition to the activities carried out as a result of recommendations of the First and Second Consultations, UNIDO pioneered in setting up the International Centre for Genetic Engineering and Biotechnology and carried out studies on: strategies and policies for the development of a domestic pharmaceutical industry; industrial and marketing aspects of factory-produced herbal medicine (case study of the Chinese experience); and women and industrialization (employment and training practices in the pharmaceutical industry in Puerto Rico).

Identification of new issues

8. UNIDO convened a meeting of experts in December 1986 on medicinal plants and other issues related to the development of the pharmaceutical industry in developing countries. The meeting reviewed the action taken to implement the recommendations of the First and Second Consultations and identified the following issues for discussion at the Third Consultation:

Issue 1: Industrial utilization of medicinal plants:
- Factory-made herbal medicine
- Technology for genetic improvement
- Process technology development and product standardization

Issue 2: International co-operation for the development of the pharmaceutical industry:
- Exchange of information and experience
- Master plan for the development of the pharmaceutical industry
- Development of pharmaceutical-related ancillary industries, with special reference to packaging materials

AGREED CONCLUSIONS AND RECOMMENDATIONS

Issue 1: Industrial utilization of medicinal plants

Conclusions

9. Herbal medicines play a vital role in the health care programmes for large segments of the world's population, especially in the developing countries; in many cases, they bridge the gap between the availability of and demand for medicines. Hence, research, development and the propagation of such medicines should be widely encouraged and in fact should be incorporated in health delivery systems.

10. Safety should be the overriding criterion in the selection of herbal medicines for human use, especially in the health service system. Different procedures for screening, chemical analyses, clinical trials and regulatory measures should be applied to the different groups of products, namely: total plants or parts thereof; crude extracts; or pure phytochemicals. Whereas a less stringent procedure could be applied to the first two groups of products, the same procedure applicable for synthetic drugs should be applied to the last group.

11. The application of modern scientific methods in the cultivation, selection, manufacturing and clinical trials of herbal medicine is the most appropriate way to transform traditional trade into modern industrial practice. In this connection, the Chinese model, along with other models that may be identified by UNIDO, could be considered by other countries when developing their own systems. Industrial production would require the adoption of appropriate agro-technology in order to obtain adequate quantities of medicinal plants of standard physical and chemical quality. There is thus a need for the large-scale cultivation of such plants and to devote attention to their genetic improvement.

12. The evolution of pilot plants for the processing of various herbal plants according to the availability and demand in various countries should be further considered, and UNIDO, in co-operation with the industry, should develop suitable designs in this respect. Research and development activities in both developed and developing countries are needed to support the development of the industrial utilization of herbal medicine.

13. There should be wider compilation and dissemination of information on the availability, properties and products generated from herbal plants. In this connection, participants from a number of countries made offers to provide assistance for research, development and training facilities.

Recommendations

Developing countries

14. It is recommended that developing countries should:

(a) Undertake, at the national level, the economic mapping of medicinal flora with a view to their use for industrial application;

(b) Establish data centres on medicinal plants and plant-derived products at the national, regional and sub-regional levels to facilitate the exchange of information;

(c) Establish national centres to carry out research and development activities in connection with the industrial utilization of medicinal plants;

(d) Include the use of herbal medicines in national health delivery systems, as well as national health education and training;

(e) Establish regulatory bodies and registration authorities for herbal products;

(f) Strengthen co-operation among the developing countries in the above-mentioned fields.

Enterprises

15. It is recommended that industries in developed and developing countries should undertake joint activities on the genetic improvement of medicinal plants and modern methods of plant propagation, including tissue culture and the standardization of plant-derived pharmaceutical products.

16. It is recommended that industries in developed countries should consider undertaking joint endeavours with developing countries for the pooling of technology relating to the production of plant-derived pharmaceuticals and their marketing.

International organizations

17. It is recommended that international bodies, including UNIDO and the World Health Organization (WHO), should:

(a) Assist developing countries in conducting pharmacological and clinical trials on plant-derived products to ensure regulatory requirements for safety and quality standards;

(b) Conduct special educational programmes to publicize the proper use of plant-derived herbal medicine;

(c) Organize consultations at regional levels on various facets of the medicinal plant industry, with special emphasis on quality standards and safety, with a view to promoting the wider use and acceptability of herbal medicines.

18. It is recommended that UNIDO should, in collaboration with other United Nations agencies, as appropriate:

(a) Develop suitable designs of pilot plants for process technology according to requests from developing countries;

(b) Provide a list of existing data bases with information on medicinal plants and assist national Governments, upon request, in the establishment of data bases on all aspects of medicinal plants and in the exchange of information between countries, directed towards the establishment of regional and interregional networks, using as far as possible existing data bases at the Food and Agricultural Organization of the United Nations (FAO), the United Nations Educational, Scientific and Cultural Organization (UNESCO), WHO, UNIDO etc;

(c) In collaboration with other appropriate organizations, initiate and expand programmes for the conservation of endangered medicinal plants;

(d) Actively promote manpower development in all facets of the industry related to medicinal plants, in industry as well as in research and development institutions.

Issue 2: International co-operation

Recommendations

Exchange of information and experience

Policy recommendations directed to national Governments

19. It is recommended that:

(a) National centres, where needed, should be established for information, manpower training and research and development related to the development of the pharmaceutical industry;

(b) Appropriate measures should be taken to enhance the linkage between the pharmaceutical industry and scientific and technological institutions.

Recommendations directed to industry

20. It is recommended that:

(a) Federations/associations of pharmaceutical producers should be established where they do not exist and where this would be appropriate;

(b) Meetings should be organized, as required, among representatives of industry and other concerned parties on a subregional, regional and interregional basis to review current activities and co-ordinate future co-operation;

(c) Information booklets relating to the activities of the pharmaceutical industry should be compiled and disseminated;

(d) Contacts should be established and maintained on a continuous basis between the pharmaceutical industry and appropriate international organizations such as WHO and UNIDO.

Recommendations directed to national and international organizations, including United Nations agencies for technical co-operation

21. It is recommended that action should be taken in the following areas:

(a) Manpower training and transfer of technology:

(i) Training workshops should be set up, as required, on operational and technical aspects of the pharmaceutical industry. Topics such as quality assurance systems, standards and specifications, technological improvement and packaging materials would be among the subjects thus covered;

(ii) The use of existing training facilities in developing as well as in developed countries should be optimized in the technical co-operation programmes of international organizations;

(iii) Industrial programmes for the rehabilitation and maintenance of existing pharmaceutical plants should be implemented in order to

increase their capacity utilization, taking into account the criteria of economic viability;

(iv) Appropriate international organizations should collaborate closely in promoting the international availability of pharmaceutical raw materials, intermediates and finished products.

(b) Exchange of information and experience:

(i) Measures should be continued with a view to enhancing the exchange of technical information on such areas as sources of supply, sources of training, quality control laboratories, specifications, production technology and aspects relating to management and marketing;

(ii) The feasibility of conducting technical audits to improve the performance of manufacturing plants should be considered.

(c) Technical and expert group meetings:

(i) Expert panels should be convened as appropriate by concerned international organizations to exchange experience in various fields related to the pharmaceutical industry.

(d) Utilization of existing R and D centres:

(i) Increased advantage should be taken of the services and facilities offered by the International Centre for Genetic Engineering and Biotechnology;

(ii) Full use should be made of the facilities for training, research and other activities offered by various countries and organizations.

Integrated development of the pharmaceutical industry

22. It is recommended to Governments, industry and international organizations, in so far as each is concerned, that, as appropriate:

(a) There is a need to study the totality of requirements for the development of the pharmaceutical industry (technology, infrastructure, manpower, investment, state of the industry etc.) and how these requirements can be met in the short, medium and long term;

(b) Pharmaceutical production strategies should be formulated, taking into account the availability of local resources as well as health aspects, giving due consideration to regional production and export potential and the development of an industrial policy that supports domestic production and stimulates exports;

(c) Steps should be initiated towards the formulation of a plan for the development of an integrated pharmaceutical industry, covering the production of pharmaceutical chemicals, formulations, biologicals and ancillary materials etc., taking due account of the experience of developed and developing countries in this regard;

(d) The assistance of international organizations might be sought in drawing up such plans and in organizing investment forums for their implementation;

(e) In view of the importance of pharmaceutical, ancillary and associated industries and activities, an integrated approach towards their development should be adopted.

I. ORGANIZATION OF THE CONSULTATION

Opening of the Consultation

Statement by the Director-General of UNIDO

23. The Director-General of UNIDO pointed out that, since pharmaceutical products were essential to ensuring both the immediate and long-term welfare of society, UNIDO had been devoting considerable efforts and resources to strengthening the pharmaceutical industry. There were, however, numerous constraints facing the developing countries that wished to develop that industry, such as inadequate technological infrastructure, restricted access to technology, the high cost of active ingredients and their intermediates and the lack of investible resources. The Director-General emphasized the importance of co-operation at both the national and international levels. UNIDO efforts at the international level included close co-operation with WHO, the United Nations Children's Fund (UNICEF) and other intergovernmental and non-governmental organizations. UNIDO attached particular importance to promoting direct interaction between representatives of industry and between industry and Government at both the national and enterprise level, thereby stimulating industrial investment. Thus, UNIDO acted as a focal point, provided information and technical assistance and acted as a forum through which companies could channel technology packages and work out licensing and joint-venture arrangements. The Director-General noted that, for the first time, the agenda of a Consultation meeting would include not only a discussion of global trends and issues but also formal arrangements to facilitate negotiations on industrial investments and technical co-operation projects.

Statement by the Minister of Health and Consumption

24. The Minister of Health and Consumption of Spain noted that the primary objectives of a public health system were to treat patients, ease pain and cure disease. He outlined the types of co-operation that were necessary to achieve those objectives, namely: scientific co-operation, to encourage research and the discovery of new products; co-operation between industrialized and developing countries to bring about a fairer distribution of the benefits of medical treatment and of production capacities; co-operation between enterprises at all levels; co-operation between administrative authorities, above all ministries of industry and health, to ensure that industrial development objectives were achieved; and co-operation between health systems and the pharmaceutical industry, in order to search for and provide increasingly safe and effective treatment. The Minister pointed out that imaginative steps needed to be taken in order to overcome the financial constraints facing health systems and to benefit all countries.

Statement by the Minister of Industry and Energy

25. In his opening statement, the Minister of Industry and Energy of Spain said that his country was convinced that international co-operation made a direct and very important contribution to world economic and social progress and was an essential feature in the overall development process. Spain was therefore making an effort to achieve integrated development that went beyond national boundaries and to increase relations with other countries. He drew attention to the role of various international bodies in regulating and

promoting the development of the developing countries and in obtaining support from the international community. Spain, he noted, had not only participated actively in the System of Consultations but also continued to collaborate with UNIDO by providing experts and organizing regional meetings. The Minister emphasized that international industrial co-operation was particularly relevant in the field of pharmaceuticals, although the health and social aspects of pharmaceutical production went far beyond the industrial and economic aspects of the industry. In order to achieve the health targets set by WHO, it would be necessary to examine the production structure of the pharmaceutical sector and adopt a framework for global action. The Minister outlined the evolution that had taken place in the Spanish pharmaceutical industry since the mid-1970s and explained that the Government continued to support that industrial sector by strengthening pharmaceutical research and improving business structures by establishing an industrial framework in order to achieve a balance between foreign capital enterprises and the consolidated national pharmaceutical industry. He noted that, because of Spain's recent integration into the developed world and the resultant awareness of the needs of the less industrialized countries, Spain was in a unique position to collaborate with developing countries, and he expressed his country's willingness to find ways of reconciling the varied aspects of the pharmaceutical industry within the framework of UNIDO as well as to continue to promote the development of the pharmaceutical industry and health in other countries.

Statement by the Director of the System of Consultations Division

26. The Director of the System of Consultations Division, in drawing attention to the importance of the pharmaceutical sector and the need for the local production of pharmaceuticals in developing countries, emphasized the importance of co-operation at the national level between ministries of industry and health; co-operation between countries, especially the developing countries themselves; and co-operation between such international organizations as WHO and UNIDO. He noted that, since the Second Consultation on the Pharmaceutical Industry at Budapest in 1983, there had been a new orientation in the System of Consultations, giving priority to international co-operation that respected the interests of the countries concerned. He also drew attention to the importance of consultations in formulating technical assistance projects and to the conclusions and recommendations reached by the participants from countries with different economic systems, at different stages of development and with different experiences. The Director drew attention to the intention of the Government of Portugal to create an international research centre within its industrial technology laboratory, which would be put at the disposal of UNIDO and the international community. Another excellent example was the co-operation given by the Government of France in the manufacture and distribution of biological products through an African regional meeting. Other countries, he said, were also actively co-operating with UNIDO in the promotion of the pharmaceutical industry. He hoped that not only Governments but also enterprises would continue to offer such co-operation.

Statement on behalf of the Director-General of WHO

27. The Programme Manager of the Action Programme on Essential Drugs and Vaccines of WHO, in a statement on behalf of the Director-General of WHO, welcomed the co-operation and understanding that existed between UNIDO and

WHO. He pointed out that, in the context of the WHO target of Health for All by the Year 2000, the provision of essential drugs was recognized as a vital element and that the aim of WHO was to help ensure the regular availability of essential drugs of good quality at the lowest possible prices. With regard to medicinal plants, the World Health Assembly had urged member States of WHO to initiate comprehensive programmes for the identification, evaluation, preparation, cultivation and conservation of medicinal plants used in traditional medicine and to ensure quality control of drugs derived from those plants. That action, he noted, was also in line with the concerns of UNIDO. The Programme Manager noted that WHO, through its Essential Drugs Programme, was playing an increasingly important role in supporting the local production of pharmaceuticals in developing countries. He emphasized, however, that the pharmaceutical industry in developing countries had no less of a responsibility than the multinational companies to ensure that its activities were consistent with the promotion of good physical as well as economic health. The current economic and financial crisis, he said, made it even more important to review critically every proposed investment in the pharmaceutical sector, as an uneconomic drug factory could be a burden. The Programme Manager drew attention to a WHO estimate that some 1.5 billion people had no access to essential drugs and to the challenge facing the international community to provide good quality, affordable essential drugs to all.

Election of officers

28. The following officers were elected:

Chairman:	Félix Lobo Aleu (Spain), Director-General of Pharmaceuticals, Ministry of Health
Vice-Chairmen:	Patrick M. Chikusu (Zambia), Managing Director and Director of Pharmaceutical Services, Ministry of Health
	Jozsef Felmeri (Hungary), Assistant General Manager, MEDIMPEX
	Rhais M. Gamboa (Philippines), Under-Secretary, Department of Health
	José Carlos Magalhaes (Brazil), President, ALIFAR
Rapporteur:	Etienne Barral (France), Rhône-Poulenc Santé

Statement by the Chairman of the Consultation

29. The Chairman of the Consultation noted the importance of the meeting and emphasized that there could be no development without industrialization. He drew attention to the importance of the pharmaceutical industry not only in meeting human needs but also in promoting industrialization and development. He was optimistic that the development of the pharmaceutical industry would create new export possibilities and promote internal equilibrium in developing countries. New technological opportunities, in the form of new products and therapies, provided for optimism in meeting international health care

objectives. The Chairman outlined the aims of the System of Consultations, which were to promote industrialization; to bring together representatives of Governments, enterprises, and international and non-governmental organizations; and to make recommendations for further action. He drew attention to the important contribution that participants could make in that regard.

30. The Chairman drew the attention of participants to the two issues for discussion. The first was the industrial utilization of medicinal plants, in particular factory-produced herbal medicine; technology for the genetic improvement of medicinal plants; and technology hardware packages - process technology development and product standardization. With regard to the second issue, international co-operation, emphasis would be on an exchange of information and experience; a master plan for the development of the pharmaceutical industry; and the development of pharmaceutical-related ancillary industries. The Chairman also drew attention to the documents prepared for the Consultation, including discussion papers, background papers and information papers.

Adoption of the agenda

31. The Consultation adopted the following agenda:

1. Opening of the Consultation

2. Election of Chairman, Vice-Chairmen and Rapporteur

3. Adoption of the agenda

4. Presentation of the issues by the Secretariat:

   Issue 1: Industrial utilization of medicinal plants:

   - Factory-produced herbal medicine
   - Technology for genetic improvement of medicinal plants
   - Process technology development and product standardization

   Issue 2: International co-operation:

   - Exchange of information and experience
   - Master plan for the development of the pharmaceutical industry
   - Development of pharmaceutical-related ancillary industries, with special reference to packaging materials

5. Discussion of the issues

6. Conclusions and recommendations

7. Adoption of the report

8. Closing of the Consultation

9. Negotiations on industrial investments - technical co-operation projects

Establishment of working groups

32. The Consultation established two working groups to discuss the issues and to propose conclusions and recommendations for consideration at the plenary. H.K. Khan (India), was elected Chairman of working group 1, and R. Roberts (United Kingdom of Great Britain and Northern Ireland), was elected Chairman of working group 2.

Documentation

33. The documents issued prior to the Consultation are listed in annex II.

Adoption of the report

34. The report of the Third Consultation on the Pharmaceutical Industry was adopted by consensus at the plenary on 9 October 1987.

Concluding statements

35. At the closing plenary, the Government of Spain was thanked for its hospitality and for the efficient way in which the Consultation was organized, which had contributed to the success of the meeting. A number of participants drew attention to the importance of the pharmaceutical industry in promoting the health and well-being of all peoples, particularly those in the developing countries, and noted that the spirit of goodwill and understanding that had prevailed during the Consultation was a major step in the development of the industry. One representative reported the willingness of the African region to host a fourth Consultation on the pharmaceutical industry.

36. The Director of the UNIDO System of Consultations Division made reference to the many offers of and requests for technical and investment co-operation that had been made during the Consultation. He expressed thanks particularly for the offer made by Portugal to establish an international pharmaceutical research and development centre within its national laboratory. The Deputy Director-General, Department of Industrial Promotion, Consultations and Technology of UNIDO said that UNIDO would co-ordinate all such offers of and requests for assistance and assured participants that UNIDO would also follow up all the recommendations elaborated by the meeting. The representative of WHO expressed satisfaction that medicinal plants had been identified as an issue for discussion because it was an area where much additional work could be carried out. He praised the partnership between UNIDO and WHO and stressed the complementarity of their tasks. The Chairman of the Consultation, in his closing remarks, noted that the climate of trust and co-operation that was evident throughout the meeting had been the most valuable result of the Consultation.

II. REPORT OF THE PLENARY SESSION

Presentation of the issues

37. Members of the UNIDO Secretariat introduced the background papers on the issues to be discussed by the Consultation. Issue 1 concerned some key aspects in the industrial utilization of medicinal plants, including the transfer of technology for genetic improvement, factory-produced herbal medicine and process technology development and product standardization (ID/WG.466/22 (SPEC.)).

38. Issue 2 was on international co-operation related to the exchange of information and experience, the integrated development of the pharmaceutical industry and the development of pharmaceutical ancillary industries (ID/WG.466/23 (SPEC.)).

Summary of discussions

39. The Government of Spain was thanked for its generous hospitality and for providing excellent facilities and services.

40. There was wide recognition that the development of the pharmaceutical industry in many developing countries depended on both the industrial and the health care policies of a country, which had to be carefully harmonized. The presence of the Minister of Industry and Energy and the Minister of Health and Consumption of Spain at the Consultation was considered to be an excellent example of co-operation at the national level in the pharmaceutical industry.

41. It was recognized that the development of a domestic pharmaceutical industry in many developing countries depended upon government support with respect to education and training, suitable infrastructure and appropriate pricing policies in harmony with domestic industrial, economic and social objectives.

42. In the development of the industry, questions related to patent law were recognized as being important and sometimes sensitive. However, international co-operation could be successful where partners were equally interested in identifying areas of common interests.

43. The co-operation between UNIDO and WHO in the pharmaceutical sector was cited as an excellent example of international co-operation. One participant pointed out, however, that, while the pharmaceutical sector was an area of common ground between UNIDO and WHO, their objectives were not wholly complementary. In some cases, it would be more feasible for countries to buy some essential drugs on the world market than to establish domestic production facilities. It was therefore necessary for a country to decide whether its main objective was industrialization or improving the health care of its people. He suggested that there was a need for a facility where particularly least developed countries and countries with small populations could discuss that question with an independent group of experts.

44. Another participant emphasized the complexities associated with the creation of a pharmaceutical industry, where certain specific conditions with respect to science and technology, financing and education had to be met, but also a number of specific requirements incorporating product quality, control

and distribution were equally important. The compelling importance of saving life, alleviating suffering and protecting human health underscored the international community's duty to overcome those difficulties and complexities. The same participant stressed that a common will should emerge from the Consultation to discover concrete and appropriate ways to increase international co-operation, while recognizing different interests, in supporting developing countries' objectives regarding the development of their pharmaceutical industry. In that connection, the diversity of situations faced by many developing countries required a case-by-case approach. Particularly in some of the least developed countries, infrastructure was seriously deficient and many basic needs remained unsatisfied. The participant emphasized that the private and public sectors of his country would be most willing to enter into co-operation arrangements with producers in developing countries.

45. On the question of an international pharmaceutical research centre, a participant, on behalf of the Government of Portugal, indicated that his Government was prepared to offer the physical and human capacities existing in the national laboratory for engineering and industrial technology. Furthermore, the additional investment required for the establishment and operation of a centre for the pharmaceutical industry would be put in place. Such a centre could be designated a Centre of Excellence in the pharmaceutical industry by UNIDO, and arrangements could be made for UNIDO to co-operate with the Centre with respect to its programmes of technical assistance. While recognizing that such a centre would be valuable, another participant noted that the industry in developing countries would need its own domestic educational, research and development facilities to remain viable. Many member countries had facilities that could be made available to assist the domestic efforts of developing countries, and UNIDO could be a focal point in co-ordinating such joint activities, on both a regional and an interregional basis.

46. One participant drew attention to the increasing use of medicinal plants for cosmetic preparations in his country. It was noted that such cosmetics were difficult to prepare and that care had to be taken to ensure that such products did not cause any long-term ill effects.

47. Attention was also drawn to the significance of medicinal plants that grew in abundance in many developing regions and were of known therapeutic value. In that regard, the experience of a number of developing countries, including China, 1/ should be studied. One participant expressed the interest of his Government in hosting a centre or pilot plant for medicinal plants.

48. UNIDO technical co-operation activities were widely commended, with many participants indicating the ways in which the industry in their countries had benefited from such activities. Those activities had also facilitated and improved bilateral co-operation, although there was a need to improve the distribution of relevant information at the national level. With respect to

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1/ See "Better utilization of medicinal plants: the phytopharmaceutical supply system in China" (PPD.47).

information, another participant indicated his country's willingness to promote co-operation through compiling and providing details of pharmaceutical products and producers' addresses. A participant noted with approval the significant involvement of women participants in the Consultation, and commended the UNIDO Secretariat in that regard.

III. REPORT OF THE WORKING GROUP ON ISSUE 1: INDUSTRIAL UTILIZATION OF MEDICINAL PLANTS

Summary of discussions

49. The working group reaffirmed that medicinal plants as a source of therapeutic agents continued to contribute to the health care programmes and economies of both the developing and the industrialized countries. Medicinal plants were used as raw materials, generally after drying, as extracts in water or in semi-processed forms, as standardized plant extracts or as pure phytochemicals and modified molecular analogues in almost all countries of the world. Their importance, particularly in respect of an estimated 1.5 billion of the world's population 2/ that lacked access to any form of pharmaceuticals, could not be over-emphasized.

50. It was stated that the production of pharmaceutical chemicals almost invariably required sophisticated and costly technology, and developing countries should be encouraged and assisted in their efforts to produce traditional medicines on an industrial scale. Natural resources were generally abundantly available, but a scarcity of funds prompted developing countries to export their plants in crude form. China had a well-developed industry based on medicinal plants that included over 5,000 industrial manufacturing units. These were equipped with facilities for the production of plant extracts, formulation and quality control. China also had 17 research institutes for research on traditional medicine and 32 pharmaceutical research institutes that carried out research on traditional medicine. Following the recommendation of the Workshop on pharmaceutical industry (combined modern/traditional pharmacy) for promoting technical co-operation among developing countries, held at Beijing in 1982, China once again reaffirmed its willingness to host a UNIDO-China R and D centre with every facility in order to assist other developing countries.

51. Several other participants also reiterated the indisputable role of medicinal plants with regard to the world's health care effort. The point was made that although industrial processing and production would mean much to the developing countries, it had to be preceded by systematic large-scale plant propagation and cultivation. Indiscriminate exploitation of wild flora was to be discouraged, and the conservation of plant species of potential value was regarded as crucial. UNIDO was urged to join in with the United Nations Environment Programme (UNEP), WHO, the International Union for Conservation of Nature and Natural Resources (IUCN), the World Wildlife Fund (WWF), the Commonwealth Science Council and other bodies in their efforts towards conservation, particularly of endangered species of medicinal plants. WHO welcomed UNIDO as an active participant at the WHO/IUCN International Consultation on the Conservation of Medicinal Plants, which was being convened to evolve guidelines on the conservation of medicinal plant species.

2/ WHO estimate.

52. In the context of industrial usage, the importance of propagating plant species that contained economic quantities of the desired therapeutic phytochemicals was discussed. Accordingly, the need for technology transfer in the genetic improvement of plant species was emphasized, and it was recognized that developing countries needed support in: their research efforts to identify areas of maximum genetic diversity for selected important medicinal plants and related near-wild species; the collection, conservation and exchange of gene-pool material; the improvement of plant-breeding methods; the establishment of systems to ensure the continuous generation of propagating materials needed for the culture of industrially utilizable medicinal plants; and conducting studies on the biosynthetic pathways of important phytochemicals in plants with a view to evolving improved species.

53. One participant expressed satisfaction that the concern for the safety of traditional medicines was receiving attention and referred to the instances where traditional medicines had subtle dangers and had harmful effects. References were made to herbal teas that had caused nasal carcinomas and to the dangers that lay in conclusions made by people lacking epidemiological training. That observation was countered by the argument that industrially processed herbal products were safe and adequately tested and that chemical products were not safer. It was also observed that traditional medicine, however simple, was better than no medicine at all. Several participants observed that no drug could be regarded as absolutely non-toxic. The view was expressed that established drugs such as quinine were sufficiently toxic as to fail the regulatory requirements of the present day and that even such requirements were not proof of absolute safety, as evidenced by the case of thalidomide.

54. The working group discussed the question of ensuring safety in some detail. The representative of WHO stated that the Organization was no longer in doubt as to the usefulness of medicinal plants in global health care. It was logical that the safety and efficacy of all therapeutic agents should be assessed prior to their administration. Accordingly, WHO activities included measures for the transfer of technology in aspects concerning the safety of medicaments. A WHO workshop, organized at Bangkok in 1985, in collaboration with the Danish International Development Agency (DANIDA), considered that subject as well as information on toxicity, methods for the evaluation of safety, the design of clinical studies and regulatory requirements. The regulatory aspects were very much a matter for the attention of national Governments.

55. Several participants emphasized the need to advocate the use and properties of herbal medicine through national health education programmes as well as through conducting training courses for physicians and medical workers.

56. The view was also expressed that isolated studies bearing reference to toxicity of medicinal plant drugs must not be used to make generalizations. Several participants expressed the view that traditionally used preparations should be assessed for efficacy or toxicity in spite of their long usage, and direct clinical trials might be considered. The relationship to foods was mentioned, and it was considered that stringent toxicity requirements, as in the case of synthetic chemicals, sometimes bore no relationship to the case. It was suggested that UNIDO and WHO should assist national Governments to develop regulatory requirements for medicinal plant preparations, such as standard specifications for products and protocols for clinical trials.

57. Several participants elaborated on the regulatory arrangements in their respective countries for plant preparations. Such regulatory requirements depended on geographical factors. Some developed countries had devised such specifications. One participant referred to a herbal remedies act formulated and published by the countries of the eastern Mediterranean region with the collaboration of the WHO Regional Office. Another participant indicated that regulations for herbal medicines had existed in his country since 1970, and those were being updated in line with requirements of the European Economic Community (EEC). In another country, pure phytochemicals had to meet the same quality control requirements as synthetic chemicals. Plant extracts had to conform to separate requirements: 112 plant products had special licensing agreements and were therefore easily marketable. For those not included in those regulations, a complete dossier of information was needed. Another country had a separate licensing committee for registering herbal preparations as well as for registering practitioners of herbal medicine. The drying procedures for herbal preparations were also controlled in that country to ensure the necessary hygienic conditions, and a new herbal pharmacopoeia was under preparation. A participant reported that in his country medicinal plants were employed as raw drugs and aqueous extracts. Pure phytochemicals extracted from them were treated on the same basis as new drugs. The new national health plan included several herbal preparations. In another country, pure phytochemicals were treated in the same manner as synthetic drugs, but crude extracts and preparations had separate evaluations.

58. Several participants indicated the usefulness of developing guidelines for testing plant extracts, chemically as well as biologically. It was proposed that UNIDO should develop guidelines for processed products, and that WHO should prepare protocols for the evaluation of efficacy and safety. One participant supported the idea of the integration of plant preparations in national health schemes.

59. The subject of factory-produced herbal medicines was next considered. While the Chinese model as outlined in the UNIDO study was considered to be an informative guide, its applicability to the developing country situation was considered limited owing to the unique nature of the Chinese case. The working group advocated similar studies at the national level in a range of countries active in producing herbal medicines. In that connection, one participant reminded the meeting that the use of medicinal plants in Europe was long-standing, although resting on different traditions than in Asia. Quality control was very strict, and much attention was directed towards the purity and homogeneity of the raw material, with emphasis placed on the control of such substances as pesticides and heavy metals.

60. The UNIDO proposal to formulate designs for pilot plants with polyvalent capability to enable developing countries to generate process technology where needed was discussed. The proposal found general acceptance, and the need for such designs was clearly recognized. One participant felt that UNIDO should identify sources of supply of such pilot plants, as they were commercially available. Other participants expressed the view that the best commercially available plants were not specifically designed to fulfil the requirements of a developing country. France offered the services of design engineers to enable UNIDO to develop designs in conformity with the need. Argentina and India also felt that they could offer such services to UNIDO, including construction facilities.

61. The working group felt that the foremost need in developing countries, in respect of the fullest industrial utilization of herbal medicines, was manpower development and training. In a multidisciplinary exercise such as drug development from plants, several facets of training were needed.

62. It was the view of many participants that a single R and D centre would not be the answer, and several regional centres for R and D would be a more desirable alternative. Several participants made offers of support to developing countries for R and D work, including China, France, India and Italy. Ideas were expressed with regard to twinning arrangements between institutions in developing countries and counterpart institutions in industrialized countries and it was suggested that UNIDO could play a role in facilitating such arrangements.

63. Discussions also centred around the need for collating information on medicinal plants at the national and regional levels and the importance of the exchange of information between countries. It was pointed out that the undertaking to build a central data base had been explored by UNIDO and was found to be beyond the scope of its resources. Accordingly, it was felt that a network of centres of information should be initiated and should be explored in conjunction with other agencies such as FAO, UNESCO and WHO.

IV. REPORT OF THE WORKING GROUP ON ISSUE 2: INTERNATIONAL CO-OPERATION

Summary of discussions

64. National experience in the development of the pharmaceutical industry was the subject of statements made by several participants, particularly those representing the developing countries. In that context, the role of United Nations agencies, including UNIDO and WHO, in the promotion of the sector was underlined by several participants, and the need for international co-operation was stressed.

65. It was agreed that both public and private sectors had a contribution to make in the development of the pharmaceutical industry. Those two sectors, far from being mutually exclusive, were complementary and should be allowed to combine harmoniously, as was the case in several developing countries. Several participants pointed out, however, that private initiative provided an effective instrument for the development of the industry and should therefore be encouraged and that joint ventures between foreign and local companies were an efficient way to transfer technology, capital, knowledge and training. It was also pointed out that the transfer of technology should be on terms mutually acceptable to the donor and the recipient and in such a way as to ensure absorption of the technology by the recipient country.

66. Several participants from both developed and developing countries described their technological capabilities in the sector and expressed their willingness to share those technologies with developing countries. Such co-operative arrangements could also include the provision of auxiliary technical assistance in training, distribution and marketing and infrastructure.

67. Some participants recalled the basic mandate of the Consultation, which was to promote and develop the pharmaceutical industry in the developing countries. Some participants considered that the dual objective of health care and industrial development were not necessarily conflicting as they both represented fundamental elements that were fully reconcilable in overall development goals.

68. Several participants stressed that the establishment of local manufacturing facilities for pharmaceuticals must be preceded by a judicious evaluation of the economic viability of such projects. In certain countries, there was a need for storage facilities with protection against climatic factors and efficient dispatching of drugs to rural areas. In that connection, one participant noted that 30 to 40 essential drugs were not covered by patents and were produced throughout the world at highly competitive prices. In his view, it was unlikely that new producers could produce those drugs more cheaply, and it would be better to direct attention towards providing a reliable primary health infrastructure for the delivery of these drugs. Other participants emphasized that economic considerations were one among other criteria that should be taken into account in building a domestic base for industry.

69. Many participants discussed patents and licensing practices in the pharmaceutical industry. The representatives of certain Governments and industries of developing countries stressed the need to guarantee to local

companies free access to technological knowledge as a precondition for their industrial progress and to foster their technological learning process. For that purpose, they added, patent laws should not grant exclusive rights on pharmaceutical products for the time necessary to reach the above-mentioned goals. Some developing countries claimed that external pressures to change their laws involved an attempt to monopolize and to prevent the industrialization of the pharmaceutical sector. UNIDO was asked by them to invite such sources of external pressures to abandon the same. One participant pointed out that systematic denials of those rights could result in new technologies being held back from potential users, to their detriment. Participants from developed countries stressed the necessity of preserving the intellectual property rights of patent holders in order to protect the results of research and development and of trade mark holders in order to ensure the quality of the products. One participant stressed that the introduction of legislation on patents had favoured the development of R+D and the discovery of new drugs. The Chairman made reference to the comprehensive manner in which those questions were being debated at the World Intellectual Property Organization (WIPO). The representative of WIPO made a brief reference to the mandate of his Organization to promote a dialogue and appropriate universal solutions in that area and enumerated some of the activities of WIPO with regard to co-operation and the diffusion of intellectual property. He invited interested parties to make more intensive use of the opportunity for dialogue provided by WIPO.

70. With regard to the economic viability of new manufacturing units in developing countries, several participants emphasized the need to apply strict commercial criteria and to assess the benefits of large-scale production whereas most others who spoke maintained that the definition of such criteria should also include broader socio-economic benefits and were under the responsibility of local governments. Participants generally agreed that countries, irrespective of their development stage and economic orientation, should pay attention to the commercial viability of new projects, existing over-capacity and their social needs.

71. Some participants enumerated requirements for establishing a pharmaceutical industry, such as a local market, the possibility of export, government regulations on prices and the profitability of operation. Other participants stressed that, in cases where the conditions of respect for intellectual property, for capital investment and for expatriate personnel requirements were not met, the pharmaceutical sector would be hampered in its growth. Other participants pointed out that the forces shaping the pharmaceutical industry were special and quite distinct from those influencing other industries and had to be taken into consideration at the planning stage of a manufacturing unit. Furthermore, the integrated development of the industry was important.

72. Some participants stated that the ultimate goal to be pursued should be the provision of adequate health care through the wide availability of drugs to the population at large, and that drugs of pharmacopoeial quality were essential for public health. All those aspects should be examined, in addition to the possibility of manufacturing drugs locally.

73. Although the need for reducing dependency on foreign sources of supply was fully recognized by many participants, others pointed out that the aim of self-sufficiency should not be over-emphasized, since even the most advanced

countries remained dependent in certain product areas. In view of the dynamic nature of the sector, a technological lead could not be preserved indefinitely.

74. Some participants noted that a dominance of their domestic industry by transnational corporations could lead to an emergence of resentment on the part of their people, which in the final analysis would detrimentally affect the interests of those companies, and that, therefore, the establishment of a local industry could contribute to the stability of markets for pharmaceutical products.

75. Many participants expressed the view that a master plan 3/, as elaborated by UNIDO, could be of use in the development of industry. Others, however, viewed the adherence to a master plan as restrictive. Yet others felt the need for a simplified step-by-step guide that could be adapted to socio-economic conditions of particular countries and as a useful instrument of information in co-ordinating interdisciplinary activities in a sector as complex as the pharmaceutical industry.

76. One participant stated that the compilation by international agencies of a list of essential drugs could only be a minimum requirement. In such cases where drugs did not appear on such lists, that would not imply that they were not safe and not efficacious in all cases.

77. Many participants from the developed and developing countries provided an account of their technical assistance activities and programmes in the field of pharmaceuticals. Those activities were implemented through a variety of different mechanisms at both the bilateral and multilateral levels. Co-operative arrangements could be further expanded tc meet the growing needs of developing countries. One participant suggested that international co-operation should be oriented at first towards missions of experts and technical studies, the development of local technical skills and training in collaboration with industry and help in the establishment of control laboratories at the national or regional level.

78. A participant proposed that a small group should be formed with the objective of achieving the establishment of 10 industrial plants in less developed countries in the next three years as a way of showing the potential of international co-operation in the field. Participants agreed that due attention should be directed not only to the creation of new manufacturing units for pharmaceutical products but also to the rehabilitation and proper maintenance of existing facilities. The process of rehabilitation was given added importance owing to the financial constraints currently facing the developing countries, including the burden of external debt.

79. In the context of the transfer of technology, many participants were of the view that adequate training in quality control was of paramount importance. In that connection, internationally agreed standards, including the certification scheme of WHO, should be adhered to by all groups of countries, irrespective of their stage of development of industry.

3/ "Master plan for the development of an integrated pharmaceutical industry" (ID/WG.366/16 (SPEC.)).

80. A formal offer was made by a participant on behalf of the Government of Portugal, which was warmly received by the participants, to put at the disposal of the pharmaceutical industry of developing countries a research and development centre. That establishment would be fully financed and staffed by the Portuguese authorities and would be made available for potential users in the developing countries through UNIDO and other international organizations. To that end, the national laboratories for industrial organization and technology located at Queluz de Baixo would be expanded for the purpose of accommodating the specific requirements of the pharmaceutical industries of the developing countries. Similarly, other representatives from developed and developing countries offered their national training facilities for the use of those interested for the development of the pharmaceutical industry. Many participants, especially those of developing countries, welcomed the suggestion to create regional centres for the development of the pharmaceutical industry. Those centres could effectively supplement national efforts in that respect. Many participants called upon the international organizations to play a key role in the establishment and subsequent operation of those units in the developing countries.

Annex I

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Annex II

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Issue 1:	Some key aspects in the industrial utilization of medicinal plants: transfer of technology for genetic improvement; factory-produced herbal medicine; and process technology development and product standardization	ID/WG.466/22 (SPEC.)
Issue 2:	International co-operation related to: exchange of information and experience; integrated development of the pharmaceutical industry; and development of pharmaceutical ancillary industries	ID/WG.466/23 (SPEC.)

Background papers

Directory of sources of supply of pharmaceutical chemicals, intermediates, some raw materials and biologicals - based on WHO model list of essential drugs	ID/WG.466/1 (SPEC.)
Multipurpose pilot plant for the production of pharmaceutical chemicals	ID/WG.466/7 (SPEC.)
Availability, pricing and transfer of technology for pharmaceutical chemicals and their intermediates	ID/WG.466/8 (SPEC.)
The challenge of biological technology transfer to developing countries	ID/WG.466/10 (SPEC.)
The industrial utilization of medicinal plants within developing countries: Transfer of technology for the genetic improvement	ID/WG.466/13 (SPEC.)
The industrial utilization of medicinal plants within developing countries: Processs technology development and product standardization	ID/WG.466/14 (SPEC.)
International co-operation in development of pharmaceutical industry - exchange of information and experience	ID/WG.466/15 (SPEC.)
Master plan for the development of an integrated pharmaceutical industry	ID/WG.466/16 (SPEC.)

Development of the pharmaceuticals related ancillary industries in developing countries with special reference to packaging materials	ID/WG.466/17 (SPEC.)
Guidelines for the supply of medicinal plants as raw materials or processed products	ID/WG.466/18 (SPEC.)
Progress report on activities related to Consultations on the pharmaceutical industry	ID/WG.466/19 (SPEC.)
Research and development centre for information, training and development of pharmaceutical technology	ID/WG.466/20 (SPEC.)

Reference papers

Items which could be included in contractual arrangements for the setting up of a turnkey plant for the production of pharmaceutical dosage forms	ID/WG.466/2 (SPEC.)
Items which could be included in contractual arrangements for the setting up of a turnkey plant for the production of bulk drugs (pharmaceutical chemicals) or intermediates included in UNIDO list	ID/WG.466/3 (SPEC.)
Items which could be included in contractual arrangements for technical assistance for the formulation of pharmaceutical dosage forms	ID/WG.466/4 (SPEC.)
Contractual arrangements for the production of pharmaceutical chemicals or intermediates and pharmaceutical formulations (Additional clauses for inclusion in documents ID/WG. 393/1/Rev.2, ID/WG.393/3/Rev.2, and 393/4/Rev.2)	ID/WG.466/5 (SPEC.)
Factors having a bearing on industrial drug policies	ID/WG.466/6 (SPEC.)
Review of work on contractual arrangements for the production of pharmaceutical chemicals, their intermediates and formulations	ID/WG.466/9 (SPEC.)
Data base for medicinal plants	ID/WG.466/11 (SPEC.)
Women in the pharmaceutical sector - a case study of the experience of Puerto Rico - summary	ID/WG.466/12 (SPEC.)
A study to assist in improving management skill for procurement of pharmaceutical chemicals, their intermediates and drugs (pharmaceutical formulations)	ID/WG.466/21 (SPEC.) and Add. 1
Model programme for the production of vaccines in developing countries	IO.2

New approaches to vaccine development - World Health Organization

Report of expert group meeting on medicinal plants and other issues - pharmaceutical industry IPCT.20 (SPEC.)

Better utilization of medicinal plants: The phytopharmaceutical supply system in China PPD.47

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