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Third Consultation on the  
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AVAILABILITY, PRICING AND  
TRANSFER OF TECHNOLOGY FOR PHARMACEUTICAL CHEMICALS  
AND THEIR INTERMEDIATES

Background Paper

Prepared by

the UNIDO Secretariat

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## I. INTRODUCTION

1. In order to identify the issues for the Consultations on the Pharmaceutical Industry, UNIDO convened two panel meetings in July 1977 and March 1978 with participants from developed and developing countries. Thereafter, an interregional meeting of experts from developing countries was convened in January 1979 with observers from the industry. Their recommendations on the issues were reviewed by the Global Preparatory Meeting for Consultation in April 1980 which finally recommended the issues for the First Consultation held in December 1980 in Lisbon and were as follows:

Issue 1: The pricing and availability of pharmaceutical chemicals and their intermediates

Issue 2: (a) Contractual arrangements for the production of pharmaceuticals covering preparation of guidelines for licensing arrangements for the transfer of technology and (b) relevant issues to be taken into account when negotiating a transfer of technology agreement

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

2. The above 3 issues were discussed at length at the First Consultation and a number of recommendations were made and implemented by UNIDO.

3. During the course of implementation of the above mentioned three issues and as a result of the discussions and recommendations of the expert panel meeting two additional issues emerged, namely medicinal plants and biologicals. In the meantime two of the previous issues were merged in one. The four issues presented for discussions at the Second Consultation held in November 1983 in Budapest were the following:

Issue 1: Contractual arrangements for the production of drugs (pharmaceutical chemicals and formulations)

Issue 2: Availability, pricing and transfer of technology for bulk drugs (pharmaceutical chemicals) and their intermediates

Issue 3: The development of drugs based on medicinal plants

Issue 4: Biologicals - the manufacture of vaccines in the developing countries.

4. This paper deals with the Issue 2: AVAILABILITY, PRICING AND TRANSFER OF TECHNOLOGY FOR BULK DRUGS (PHARMACEUTICAL CHEMICALS) AND THEIR INTERMEDIATES of para 3.

## II. BACKGROUND

5. The issue of Availability and pricing of pharmaceutical chemicals (bulk drugs) and their intermediates remains as one of the most important factors having bearing on the supply as well as the local production of

pharmaceuticals in developing countries. The issue covers two main topics, namely intermediates required for manufacture of pharmaceutical chemicals (bulk drugs) and pharmaceutical chemicals required for formulation into dosage forms.

6. The past Consultations recognized that high prices of intermediates had direct impact on the prices of pharmaceutical chemicals. At times, prices of intermediates are higher than the prices of pharmaceutical chemicals which adversely affected the economy of both pharmaceutical chemical production and pharmaceutical formulations into dosage forms. Thus the features characterizing this issue were:

- (i) the existing disparity between prices of pharmaceutical chemicals (bulk drugs) and their intermediates, and
- (ii) prices of intermediates as a constraint to producing pharmaceutical chemicals and formulations in dosage forms.

7. The Committee of Experts on Pharmaceuticals constituted in 1981 in line with the terms of reference agreed by the First Consultation discussed the issue at length but could not recommend any pricing mechanism that can be used as an international yardstick for the assessment of prices hence no mechanism or regulation for pricing could be suggested at the Second Consultation.

8. However, in view of the importance of this issue the Committee of Experts on Pharmaceuticals suggested two approaches for improving the availability and pricing aspects which were as follows:

- (i) Production of bulk drugs (pharmaceutical chemicals) and intermediates in developed countries to meet the collective requirement of interested developing countries
- (ii) Production of bulk drugs (pharmaceutical chemicals) and intermediates in developing countries through transfer of technology.

9. In response to a questionnaire on (i) above and as part of the follow up actions to ascertain collective requirements, some developing countries expressed certain reservations about the lack of information on sources of supply, criteria for purchase and the problems of tied loans, etc. In a few cases pharmaceutical plants were made idle due to high prices of imported intermediates and/or outdated technology. Certain developing countries stated that this ascertainment contradicts the spirit of transfer of technology.

10. The compilation of Directory of sources of supply for pharmaceutical chemicals (essential drugs) and their intermediates was foreseen as an instrument contributing to the provision of information on alternative sources of supply and thus to somewhat alleviating the above situation and assisting in resolving the problems associated with availability of sources and also indirectly that of pricing

11. While considering 8.(ii) above i.e. domestic production of pharmaceutical chemicals and their intermediates in the developing countries, the Committee of Experts observed that local production is invariably linked with transfer of technology and effectively the issue regarding transfer of technology serves as tool for solving the problem of availability and pricing of pharmaceutical chemicals and their intermediates.

12. Therefore, it was deemed proper that effective issues of availability, pricing and that of transfer of technology has close linkage and should be merged in one issue for subsequent discussions and implementation.

13. In dealing with the Transfer of technology to manufacture 26 essential drugs (pharmaceutical chemicals) included in UNIDO's list and their intermediates the Consultations recognized that developing countries by and large constituted bigger markets for the 26 pharmaceutical chemicals (essential drugs) identified by UNIDO. However, those countries experienced difficulties in obtaining suitable technology based on intermediates and/or raw materials directly obtainable in the world market or locally procured.

14. Participants from developed countries and the international industry expressed willingness to transfer technology under mutually acceptable terms in order to enable developing countries to produce the 26 drugs identified in UNIDO's list of essential drugs.

15. The Second Consultation recommended that UNIDO should continue its efforts to obtain information identifying technology holders and recipients and circulate such information and prepare feasibility studies at the request of interested countries.

16. The problem of availability, pricing of pharmaceutical chemicals and their intermediates and technology to manufacture them in the developing countries has been handled through approaches of multidimensions. The past Consultations have been aiming to improve the sources of supply, procurement skill and also find ways to build up the capabilities for domestic production of pharmaceuticals in the developing countries.

### III. FOLLOW UP ACTIONS ON THE RECOMMENDATIONS OF THE SECOND CONSULTATION

17. In implementing the recommendations of the Second Consultation on the issue of availability, pricing and transfer of technology aiming to assist in the development of pharmaceutical industry, UNIDO, as far as resources permit, has prepared a number of studies and carried out surveys on sources of supply for pharmaceutical chemicals, intermediates, and availability of technology. UNIDO has endeavoured to put technology recipients in contact with technology holders/transfersors, and assisted in providing technical assistance and conducting feasibility studies leading to transfer of technology for the production of pharmaceutical chemicals and pharmaceutical formulations. A moderate degree of success was achieved in this sphere during the last three years.

18. UNIDO prepared a series of documents and took action in support of this issue including:

- Enlarged directory of sources of supply for pharmaceutical chemicals and their intermediates covering 100 essential drugs included in WHO model list of essential drugs,
  - Study to assist developing countries to improve management skill for the procurement of pharmaceutical dosage forms, pharmaceutical chemicals and their intermediates,
  - Study highlighting factors having bearing on industrial drug policy of assistance to developing countries
  - Revision of technical profiles for the establishment of pharmaceutical formulation units
  - Survey on transfer of technology, bringing together technology transferors and recipients
  - Paper on master plan for integrated development of pharmaceutical industry
  - The role played by the multipurpose plant for the manufacture of pharmaceutical chemicals
- Set of studies covering technical and economic analysis of the manufacture of selected pharmaceutical chemicals
- Steps taken towards the establishment of R&D Centre for the pharmaceutical industry, and
  - Set of documents on contractual arrangements related to transfer of technology.

For further details participants attention is drawn to the list of documentation presented on the above and available to this Consultation.

19. In line with the recommendations of the Second Consultation the Directory of Sources of Supply for Pharmaceutical Chemicals and their Intermediates mentioned above was enlarged on the basis of a survey covering 400 manufacturers and suppliers. It covers now 100 pharmaceutical chemicals needed to manufacture essential drugs included in the WHO model list of essential drugs and their intermediates. The Directory is expected to assist developing countries in obtaining their requirements of pharmaceutical chemicals and their intermediates and in enlarging trade collaborations leading to competitive buying and economic production resulting in improved drug delivery and health programmes. UNICEF has in its plans the routine publication of indicative price lists for pharmaceutical chemicals which is a valuable supplement to this work.

20. To assist in enhancing and improving the management skills for procurement in developing countries a study was carried out highlighting the problems related to procurement, general means for improved procurement, procurement structures, procurement costs and practices, UNICEF procurement system, etc.

21. A study highlighting the factors having a bearing on industrial drug policy based on survey of various studies and reports produced by United Nations agencies (UNCTAD, UNCTC, UNIDO and WHO). It covers exhaustively all factors related to industrial drug policy having bearing on the development of domestic pharmaceutical industry.

22. The technical profiles for the establishment of pharmaceutical formulation units which was presented to the Second Consultation have since been revised giving additional information on design, layout of model production units, production steps, equipment, etc. (ID/WG.393/14/Rev.1).

23. In order to prepare a study on transfer of technology two separate questionnaires were sent to 325 pharmaceutical producers and organizations in developed and developing countries. One was addressed to transferors of technology and the other was addressed to prospective recipients of technology for the manufacture of pharmaceutical formulations, pharmaceutical chemicals and their intermediates. The Annex I gives tabulated results of the survey. The prospective technology recipients were advised about the particulars of the technology holders/transferors and vice versa for further negotiations. Six prospective recipients are reported to have made contacts with technology holders. UNIDO has assisted two countries in making feasibility studies and assistance was provided in effecting transfer of technology.

24. The technology transfer handled through UNIDO technical assistance programme to developing countries was more at pilot plant level. By and large deployment of multipurpose plants for the production of pharmaceutical chemicals is a step in the right direction. The concept of setting up multipurpose plant serves as a strategy to enter flexible manufacture of number of pharmaceutical chemicals and most important for creating facilities for know how, transfer of technology, R+D and production capacities. Still it seems prudent that access to high technology, meeting the challenge of high cost for the same and achieving true economic production would need concerted efforts by the developing countries in considering a coordinated development plan at regional level for the production of pharmaceutical chemicals and their intermediates. Such an effort of cooperation between developed and developing countries, and among developing countries themselves, would help to resolve the problem more effectively.

25. To complement the efforts UNIDO simultaneously undertook a set of studies covering technical and economic analysis of the manufacture of 3 selected pharmaceutical chemicals covering Chloroquine Phosphate (UNIDO/IS.518), Isoniazid (UNIDO/IS.622), Ethambutol (UNIDO/IS.588). These studies came up with technical and economic feasibility of domestic production of pharmaceutical chemicals and intermediates specific to these drugs.



26. Action was taken by UNIDO with the Government of Portugal and with other countries with regard to the setting up of R&D Centre for pharmaceutical industry. It included preparation of a prefeasibility study and thereafter investigation to reascertain the interest of member states in establishment of the Centre. In response to the Secretariat's enquiry on the matter about 65 countries have so far indicated their views on the setting up of the Centre which include 30 expressing strong interest, 32 wanting additional information on the matter and 3 not in favour. If the decision is reached towards the creation of the Centre, undoubtedly it would assist to enhance technological and managerial capabilities in the field of pharmaceuticals.

### Annex I

#### Report of UNIDO's Survey on Transfer of Technology for the Production of Essential Drugs

Number of Technology Holders who indicated the availability of technology for the production of pharmaceutical formulations, pharmaceutical chemicals and their intermediates

	Pharmaceutical formulations	Pharmaceutical chemicals	Intermediates
Developed Market Economy Countries	23	36	7
Centrally Planned Economy Countries	2	3	3
Developing Countries	19	22	9

Number of prospective Technology Recipients who indicated requirement for technology

	Pharmaceutical formulations	Pharmaceutical chemicals	Intermediates
Developing Countries	29	36	8