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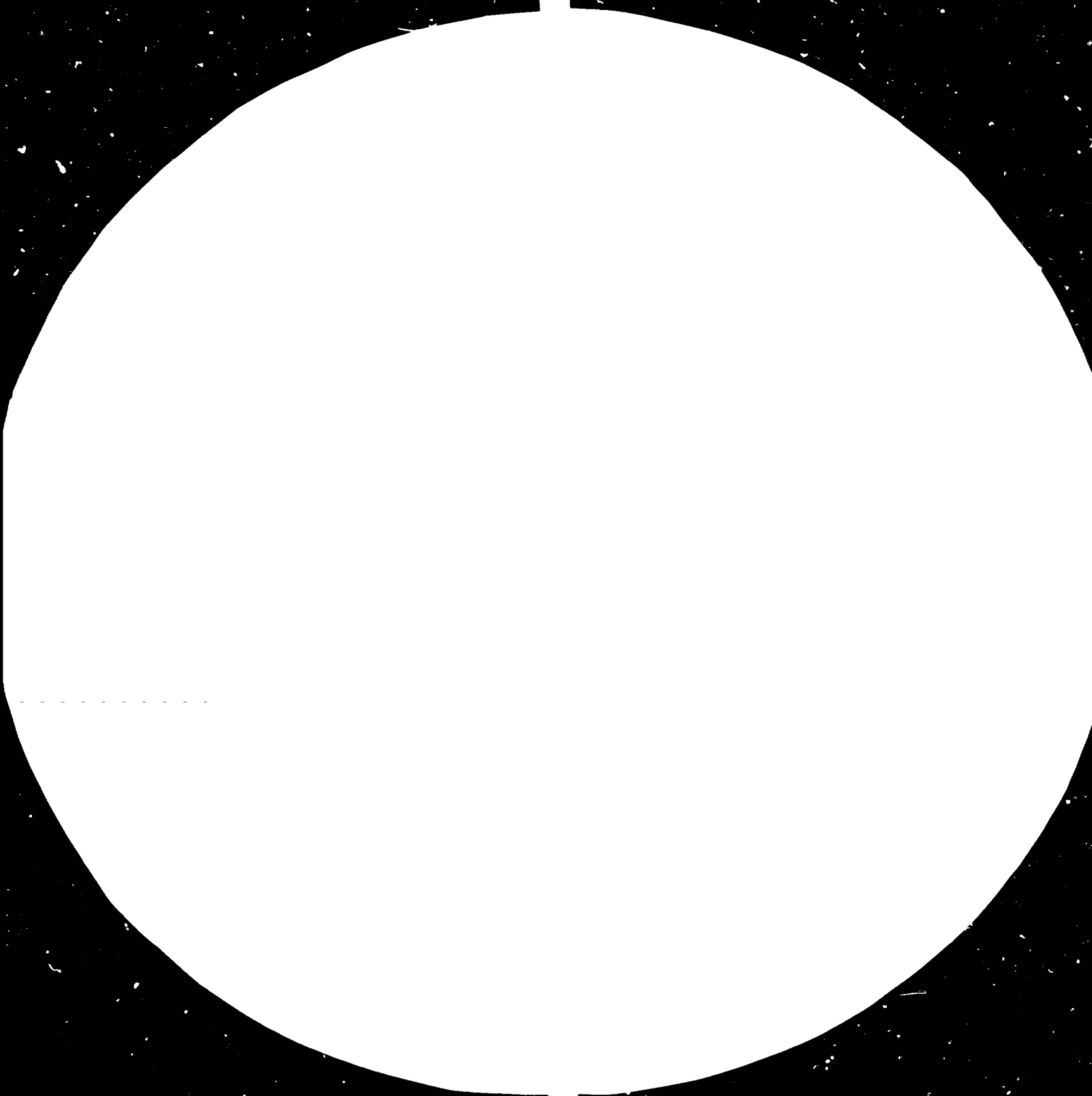
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AVAILABILITY, PRICING AND
TRANSFER OF TECHNOLOGY FOR
BULK DRUGS AND THEIR INTERMEDIATES,

Background paper *

prepared by
the UNIDO secretariat

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INTRODUCTION

1. The First Consultation on the Pharmaceutical Industry recommended the setting up of a UNIDO Committee of Experts on Pharmaceuticals selected on the basis of equitable geographical distribution, to discuss the technical and economic aspects of the availability of intermediates and bulk drugs.

In particular, the Committee will be dedicated to evolving a better understanding of matters relating to the availability of the 26 essential drugs included in UNIDO's list, and to assisting developing countries in the production of these bulk drugs and its intermediates.

UNIDO was also requested to prepare a directory of sources of supply of essential drugs from developing and developed countries.

2. The First Consultation further recognized that the 26 essential drugs in UNIDO's list and other well defined medicinal plant-based products, constitute a suitable list for undertaking its basic manufacture in developing countries, and for which they have a bigger market. Developed countries and the international pharmaceutical industry expressed their willingness to enable the transfer of technology to developing countries to manufacture the above drugs/products under mutually acceptable and equitable terms, including its upstream manufacturing integration to raw materials.

UNIDO was requested to facilitate such mutually acceptable transfer of technology by providing relevant information which could be a significant aid to individual developing countries in bilateral negotiations for transfer of technology.

3. The First Consultation also agreed that co-operation among developing countries could play an effective role in the development of the pharmaceutical industry in developing countries.

4. As follow-up to the above agreements and recommendations, UNIDO carried out in 1981 a survey on drugs for which technology could be offered, by addressing technology-holders according to the willingness to transfer technology expressed in para. 2 above. The results obtained were unsatisfactory due to a poor response on the questionnaire.

5. Simultaneously, UNIDO convened a Round Table Meeting on the Development of the Pharmaceutical Industry at Mohammedia, Morocco in December 1981, to advise UNIDO on terms of reference to discuss the availability and pricing of bulk drugs and intermediates, the composition of the Committee of Experts and the directory of sources of supply of the 26 essential drugs included in UNIDO's list.

6. The Committee of Experts on Pharmaceuticals was convened in Paris, France in October 1982 to discuss the technical and economic aspects of the availability and pricing of bulk drugs and intermediates, and to review a draft directory of sources of supply of the drugs included in UNIDO's list.

To implement the recommendations of the Committee, two surveys, several studies and the compilation of the directory of sources of supply were carried out.

In addition, a meeting on co-operation among developing countries in pharmaceuticals is being convened at Tunis, Tunisia early September 1983. The recommendations of this meeting will be presented at the Second Consultation.

The overall presentation of the issue is given at the end of this paper.

I. ROUND TABLE MEETING ON THE DEVELOPMENT OF THE PHARMACEUTICAL INDUSTRY

7. The Round Table Meeting was convened at Mohammedia, Morocco, from 2 to 3 December 1981. It was attended by 22 participants from 15 countries and the industry (report: UNIDO/PC.33).

8. In presenting the issue, the following features were highlighted:

a) Availability and pricing of bulk drugs and intermediates (issue 1)

The issue covers two topics, intermediates required for manufacture of bulk drugs and bulk drugs required for formulations into dosage forms.

The First Consultation recognized that high prices of intermediates had direct impact on the prices of bulk drugs. At times, prices of intermediates were higher than prices of bulk drugs which adversely affected the economics of both drug production and formulations into dosage forms.

The compilation of a directory of sources of supply of bulk drugs and intermediates may contribute to alleviate somewhat the above situation.

b) Transfer of technology to manufacture the 26 essential drugs included in UNIDO's list (issue 3)

The First Consultation recognized that developing countries constituted a bigger market for the 26 essential drugs identified by UNIDO. However, those countries experienced difficulties in obtaining suitable technology based on intermediates and/or raw materials.

Participants from developed countries and the international industry expressed willingness to enable the above transfer of technology under mutually acceptable terms. Nevertheless, the results of the UNIDO survey on this matter (para. 4) indicated the seemingly non-availability of technology for the production of the 26 bulk drugs and their intermediates.

9. The conclusions and recommendations of the meeting were the following:

- a) Since the First Consultation recognized the existence of a problem concerning prices of bulk drugs and intermediates, the Committee of Experts to be established should pay particular attention to those bulk drugs and intermediates for which there are only limited sources of supply, with a view to improve their economic availability at mutually acceptable terms and conditions so as to assist developing countries in the successful production of bulk drugs and intermediates.

Nine drugs out of the UNIDO's list of 26 essential drugs were identified as having limited sources of supply, and for which the establishment of manufacturing facilities in developing countries is a matter of priority. Annexure A presents such a list.

- b) The Committee of Experts should include representatives from those manufacturers of bulk drugs and intermediates for which there are limited sources of supply.
- c) UNIDO should prepare a directory with names of manufacturers and suppliers of the 26 essential drugs and their intermediates, including details and specifications. Whenever requested by a developing country to provide information on indicative prices for those essential drugs, UNIDO will use its best endeavours to do so. The directory may also include similar information on additional essential drugs needed by developing countries. The directory should be updated periodically.

II. MEETING OF THE COMMITTEE OF EXPERTS ON PHARMACEUTICALS

10. Upon the advice of the Round Table Meeting, the Committee of Experts on Pharmaceuticals was convened in Paris, France from 11 to 13 October 1982. It was attended by 16 participants from 13 countries (report: UNIDO/PC.59). The list of members of the Committee of Experts is given in Annexure B.

A. PRESENTATION OF THE ISSUE

11. The UNIDO Secretariat clarified the constitution of the Committee of Experts, specifically emphasizing that the participants represented the pharmaceutical industry, including those concerned with the manufacture of one or more intermediates related to the nine essential drugs having limited sources of supply.

In presenting the issue the Secretariat highlighted the main features of issue 1 of the First Consultation and its findings on issue 3, transfer of technology (see para. 8) and introduced the documents for the meeting.

- a) The main features of the issue are the following:
 - i) the existing disparity between prices of bulk drugs and their intermediates,
 - ii) prices of intermediates were a constraint to producing bulk drugs and formulations into dosage forms in developing countries,
 - iii) the non-availability of technology for the production of the 9 essential drugs and their intermediates.

- b) Two main documents were presented to the meeting for discussions:
 - i) Availability, pricing and technology of essential drugs and their intermediates (report: UNIDO/PC.52).

- ii) draft directory of sources of supply of bulk drugs, their intermediates and some raw materials (report: UNIDO/PC.51) and its addendum (UNIDO/PC.51/Add.1).

12. The first paper, "availability, pricing and technology of essential drugs and intermediates", updates two earlier documents presented at the First Consultation (ID/WG.331/4) and at the Round Table Meeting (UNIDO/PC.14). The paper considers the development of new trends, the impact of those trends on the establishment of basic drug manufacturing facilities in developing countries and the appraisal of other significant factors besides the price of intermediates on the economic feasibility of domestic drug production. In addition, the paper reviews the pricing scheme presented in the two earlier documents referred to above and which may have been considered as a price regulator for intermediates. The pricing scheme presented to the First Consultation was a mechanism for evaluating the relationship between the cost of intermediates and the cost of producing bulk drugs. The scheme was used by UNIDO to analyse the impact of prices of intermediates on the production cost of bulk drugs; this scheme should in no way be interpreted as a formula to arrive at fixed prices for intermediates.

13. The updated paper on "availability, pricing and technology of essential drugs and intermediates" reconfirms the conclusions reached in the two earlier documents, and which are the following:

- a) basic drug manufacture in developing countries only becomes economically viable when prices of intermediates are reasonable in relation to the production cost of drugs, hence the availability and price of intermediates is by far the most important factor in the economics of drug production.
- b) In the last 5 years the economic feasibility of domestic production of some essential bulk drugs has been improved while in other drugs it showed adverse trends. The main factor responsible for those variations was the change of

prices of intermediates, price decreases in the former and price increases in the latter. It also showed that some reductions were possible in the cost of domestic raw materials and in conversion costs.

- c) The availability of up to date technology was also identified as an important factor leading to greater cost efficiency in drug production.

14. The second paper, the "directory of sources of supply of bulk drugs", was compiled in accordance with the recommendations of the First Consultation and the Round Table Meeting. It is a first step towards assisting developing countries in obtaining their requirements of pharmaceuticals at the best possible prices and on the most suitable delivery schedules.

The addendum to the directory presents a mathematical concept that illustrates the price relationship between intermediates and bulk drugs. This mathematical formula, which is not intended for use as an international yardstick, could serve to bring a given situation to transparency and to compare certain techno-economic aspects of alternative technologies.

B. SUMMARY OF DISCUSSIONS

1. Availability, pricing and technology of drugs and intermediates

15. Participants from developed countries indicated that the global economic recession was severely affecting the pharmaceutical industry concerning new investments, lower profits and government efforts to control health-related expenditures. During the 1970s, large capacities were built and some of which became idle, thus resulting in temporarily lower prices; this situation was not expected to last long.

A participant from developing countries commented that similar economic difficulties were faced by these countries.

16. A participant from a developing country requested an explanation to the case presented in the updated paper, namely that the prices of intermediates for ethambutol and isonizid had fallen and yet, the international prices of these two bulk drugs had remained stable. A participant from a developed country commented that the paper presented the experience of only one country and may not be applicable to other developing countries.

17. Participants from developed countries further commented that a generalized method for establishing relationships between prices of intermediates and bulk drugs could neither be found nor would it be helpful. Discussions should be concentrated on specific drugs and intermediates taking into account factors like investment, return on capital, research and development, etc., with the understanding that developing countries are prepared to take higher local cost than those incurred in developed countries.

18. Participants from developing countries stressed that there should be a formula available to establish relationships between prices of intermediates and bulk drugs.

A participant from a developed country commented that such formula would not take process improvements into account, and the experience of his country has shown that a fixed ratio between the price of bulk drugs and dosage form formulations has prevented a price reduction in his country. He acknowledged, however, that such formula is useful to show the existence of the problem but not to solve it.

19. A participant from a developing country felt that pricing is a temporary problem while the crucial issue is the availability of appropriate technology for bulk drugs and intermediates. He gave three possible approaches for solving this problem: competitive purchasing linked with buying technology; co-operation between developing and developed countries and among developing countries through joint-ventures or joint technology development; and technology development in developing countries by domestic research and development facilities.

20. A participant commented that multi-source availability of intermediates do not pose a serious problem to drug production. However, intermediates from limited sources of supply need the co-operation of those suppliers from developed countries concerning its availability at mutually acceptable terms and conditions to enable the economic production of bulk drugs in developing countries.

Similarly, bulk drugs from limited sources of supply and which are used predominantly in developing countries, require the co-operation of those suppliers from developed countries to make such drugs available to developing countries at reasonable prices.

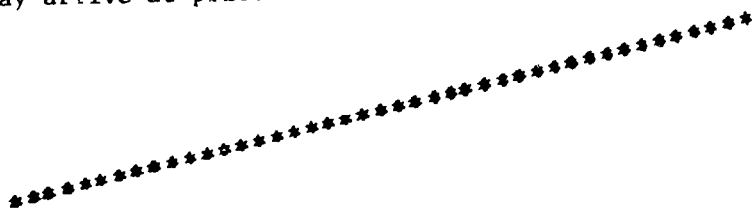
21. Few participants from developing countries indicated that when manufacturing facilities for certain bulk drugs were established in some developing countries, these drugs were offered by developed countries at very low prices without any relationship to the prices at which their intermediates were made available. This situation is overstressing the economic viability of continuing production of these drugs in developing countries. In some cases, drug manufacturing facilities have already been idled or closed down.

2. Directory of sources of supply and addendum

22. There was a general appreciation on the usefulness of the Directory. Participants suggested that the Directory could also include indicative prices, distinguish manufacturers from suppliers, and would require periodic updating.

In addition, the Directory should indicate pharmacopoeial references relating to sources of supply, including storage requirements in particular for heat sensitive substances.

23. Regarding the addendum, a participant warned that users of the price formula may arrive at prices which are not attainable in the market.



UNIDO explained that the primary intention of the addendum is to describe the method used in arriving at the desirable prices given in the first paper on "availability, pricing and technology of essential drugs and intermediates". Some variables of the formula are complex and represent the sum of several elements. Conclusions drawn with the use of this scheme are justified only if the data used for the calculation is correct and represent the techno-economic standards of the process described.

C. CONCLUSIONS AND RECOMMENDATIONS

24. The Committee acknowledged the major impact of availability and pricing of intermediates in bulk drugs production and dosage form formulations in developing countries.

However, no conclusion or alternative approach was obtained concerning the pricing mechanism that linked cost of intermediates with cost of drugs. The Committee, nevertheless, took the opportunity to look for alternative solutions to the issue, which are included in the recommendations given herebelow.

25. The Committee of Experts recommended the following:

- a) With the aim to arrive at prices for intermediates which are in reasonable relationship with the cost of bulk drugs, negotiations on supply and prices of bulk drugs or intermediates should be conducted between suppliers and purchasers based on mutual acceptance.
- b) The quantitative requirements of interested developing countries should be assessed and indicated to the manufacturers. Following negotiations between purchasers and suppliers based on long-term contractual arrangements, the manufacturers should arrange the production of these intermediates and bulk drugs and ensure their supply to developing countries at reasonable and mutually acceptable prices.

- c) UNIDO, in collaboration with producers from developed and developing countries, should undertake a study based on non-confidential reference information relevant to the transfer of technology for the manufacture of intermediates and bulk drugs. Such study could significantly aid individual developing countries in bilateral negotiations for transfer of technology.

Annexure C gives the indicative list of non-confidential reference information required for conducting the study.

- d) Particular attention should be given to the specific problems of the least developed countries which are still at the first stage of their pharmaceutical development. For these countries, the problem of availability and quality control of bulk drugs and formulations including vaccines at mutually acceptable conditions and prices, is of crucial importance.
- e) The recommendations of the First Consultation regarding the transfer of technology for the manufacture of essential drugs and intermediates (issue 3), were noted.

26. The recommendations of the Committee pointed out to a two-prong alternative solution on the supply of bulk drugs and intermediates to developing countries, and to assisting developing countries in the manufacture of formulations of bulk drugs into dosage forms.

- a) production of bulk drugs and intermediates in developed countries to meet the collective requirements of interested developing countries (para. 25(b)).
- b) production of bulk drugs and intermediates in developing countries through transfer of technology. The study requested on this topic (para. 25(c)), effectively includes this issue into issue 3 "transfer of technology", since domestic production is invariable linked with transfer of technology.

- c) to assist developing countries in the manufacture of formulation of bulk drugs into dosage forms (para. 25(d)).

III. FOLLOW-UP ACTION ON THE RECOMMENDATIONS OF THE COMMITTEE OF EXPERTS

A. PRODUCTION OF BULK DRUGS AND INTERMEDIATES IN DEVELOPED COUNTRIES TO MEET THE COLLECTIVE REQUIREMENTS OF DEVELOPING COUNTRIES

27. UNIDO sent out a questionnaire to ascertain the drug and intermediate needs of a number of developing countries. Some of the countries that replied expressed certain reservations about the lack of information on sources of supply, criteria for purchases, etc. Information on intermediates was limited since in few cases bulk drug plants were idle due to high prices of imported intermediates and out-of-date technology, which rendered those plants uneconomic to operate. Further, certain developing countries stated that this ascertainment of needs contradicts the spirit of transfer of technology.

The points raised by developing countries in the above context would need particular consideration in attempting to work out a solution on this topic.

28. The compilation of the "directory of sources of supply of bulk drugs, their intermediates and some raw materials" was completed after surveying about 400 manufacturers or suppliers in developed and developing countries. The directory is expected to inform developing countries about a range of sources of supply to assist them in obtaining their requirements of drugs and intermediates, and to improve their negotiations on procurement.

B. PRODUCTION OF BULK DRUGS AND INTERMEDIATES IN DEVELOPING COUNTRIES THROUGH TRANSFER OF TECHNOLOGY

29. In order to prepare the study on transfer of technology recommended by the Committee in para. 25(c) above, a questionnaire was sent to 130 major pharmaceutical producers and organizations in developed and developing countries.

Only 14 replies were received covering 17 drugs and 2 intermediates, 20 technology holders expressed regret. Annexure D gives the tabulated results of the survey. Further, some companies requested that the information they supplied be treated as confidential and thus it should not be published.

30. The analysis on the sometimes incomplete information received in replies to the survey, shows that in most cases the technology to manufacture the essential bulk drugs in UNIDO's list were based on intermediates. Since the problem of availability and pricing of intermediates still remains unsolved, and technology to manufacture intermediates seems to be non-available, the desirable upstream integration to produce drugs from raw materials could not be achieved. Nevertheless, the aim set by the Committee of Experts, the domestic production of drugs and intermediates in developing countries, seems to be the more appropriate solution despite current setbacks.

31. Further evaluation of the data showed inadequacy of information in a number of cases. In certain instances the technology offered was not in current use by its holder.

For drugs requiring fermentation technology to manufacture, few and somewhat incomplete replies were received on tetracycline and streptomycin.

Owing to the small number of replies and limitations of data, no meaningful comparison and appraisal could be undertaken. Non-confidential information can be provided to interested developing countries on request.

32. Despite the above disappointing outcome and considering the intention of the Committee to solve this issue through production in developing countries, UNIDO continued its search and eventually became successful in identifying some independent research-based technology holders willing to transfer technology for the production of 21 out of the 26 essential drugs included in UNIDO's list.

33. To complement the survey mentioned in para. 29, UNIDO simultaneously undertook the study of technical economic and environmental aspects related to transfer of technology. These studies were the following:

- a) preparation of design and layout of a multipurpose plant for the production of UNIDO's list of essential drugs based on raw materials and intermediates.
- b) Four case studies on national drug policies of selected developed and developing countries, indicating the impact of such policies and pricing mechanisms on the development of the pharmaceutical industry.
- c) environmental aspects, in particular water use and effluents, related to the establishment of manufacturing facilities from raw materials to intermediates to drugs.
- d) strengthening of the study on "relevant topics to be taken into account in the preparatory phase of technology transfer agreements for the production of pharmaceuticals", recommended by the First Consultation under issue 2, "contractual arrangements for the production of drugs".

All the above studies have been included under reference papers to be made available at the Second Consultation.

C. FORMULATION OF BULK DRUGS INTO DOSAGE FORMS

34. The First Consultation and the Committee of Experts acknowledged the impact which the availability and pricing of bulk drugs have on establishment of manufacturing facilities to formulate bulk drugs into dosage forms. Although no specific recommendation was given for action by UNIDO except the preparation of the directory of sources of supply of bulk drugs, UNIDO undertook a study on the formulation industry.

35. In order to assist in particular the least developed countries in establishing their formulation facilities, UNIDO is preparing industrial profiles of pharmaceutical production units for formulations and bulk drugs.

The profiles on formulations include the design and layout of model production units. These profiles could serve as guidelines for the phased setting-up of production units, starting from preparations for oral use up to parenteral dosage forms and intravenous infusions.

IV. PRESENTATION OF THE ISSUE TO THE SECOND CONSULTATION

36. Upon the recommendations of the Committee of Experts, UNIDO is presenting to the Second Consultation, within the issue of "availability, pricing and transfer of technology for bulk drugs and their intermediates", the following:

- a) A report to the Second Consultation presenting the results obtained on the following:
 - (i) availability and pricing of bulk drugs and intermediates,
 - (ii) transfer of technology for the production of bulk drugs and intermediates in developing countries.
- b) A request for advice about the possibility of solving the problem of availability and transfer of technology through co-operation between developed and developing countries, and among developing countries.
- c) The directory of sources of supply of 26 bulk drugs, their intermediates and some raw materials.
- d) The reference studies mentioned in paras. 33 and 35.

37. Considering that no solution has been so far arrived at pertaining to this issue, UNIDO still hopes upon a continued fruitful dialogue with major technology holders. However, some alternative approaches have been pursued such as the identification of other sources of technology; co-operation among developing countries for, among others, the longer term development of basic drug technologies; assistance to least developed countries in formulation into dosage forms; and the need for national drug policies.

ANNEXURE A

Illustrative UNIDO List of 26 Essential Drugs

A. ANALGESICS

1. Acetylsalicylic acid *
2. Paracetamol

B. ANTI-INFECTIVE DRUGS

Anthelmintic drugs

3. Mebendazole
4. Piperazine

Antibacterial drugs

5. Ampicillin *
6. Benzylpenicillin
7. Erythromycin
8. Sulfadimidine *
9. Tetracycline *

Antifilarial drugs

10. Diethylcarbamazine *

Antileprosy drugs

11. Dapsone *

Antimalarial drugs

12. Chloroquine *
13. Primaquine

Antituberculosis drugs

14. Ethambutol *
15. Isoniazid *
16. Streptomycin

C. BLOOD PRODUCTS

17. Plasma fractions

D. CARDIOVASCULAR DRUGS

Antihypertensive drugs

18. Hydralazine
19. Propranolol
20. Reserpine

E. DIURETICS

21. Furosemide

F. DRUGS AFFECTING THE BLOOD

22. Hydroxocobalamine

G. HORMONES

Antidiabetic agents

23. Insulin

Oral contraceptives

24. Ethinylestradiol/Levonorgestrel

H. VITAMINS

25. Ascorbic acid
26. Retinol

Note: This list was prepared by UNIDO in consultation with WHO. The classification and nomenclature was updated according to WHO's "The Use of Essential Drugs", Technical Report Series No. 685.

* Selected 9 priority drugs for which sources of supply are limited (report: UNIDO/PC.33)

ANNEXURE B

LIST OF PARTICIPANTS

CHINA
Chi ZENGH
Deputy Director
Shanghai Pharmaceutical Industry Design Institute
1856 Nanjing West Road
Shanghai

Telex: 22659 SPAC CN

FRANCE
Daniel BIRET
Sous-Directeur au Ministère de la Recherche et
de l'industrie
Direction des Industries Chimiques,
Textiles et Diverses
Division Industries Pharmaceutiques
66 rue de Bellechasse
75700 Paris

Telephone: 556 55 44

Jean-Louis KEENE
Direction de la Pharmacie et des médicaments
Ministère de la Santé
8 avenue de Segur
75700 Paris

Telephone: 567 55 44

Dr. Lavaud
Roussel Uclaf
Tour Roussel Nobel
92080 Paris La Defense Cedex 3

Telex: Roussel 610884 Puteaux

Etienne BARRAL
Rhône Poulenc Santé
Cedex no. 29
92097 Paris La Defense

Telex: Rhone t 610500 F
Telephone: 768 09 05

GRECE
Jane ROUMBELAKI
Chief of Valuation in Customs Department
Customs Directorate
Ministry of Finance
6 Rethymon Street
Athens

Telex: 214001
Telephone: 32 38 657

HUNGARY János SPOLARICH
Head of Department
Union of the Hungarian Pharmaceutical Industries
Lehel u. 11
1134 Budapest

Telex: 224485
Telephone: 490 331

INDIA S. RAMANATHAN
Secretary
Ministry of Chemicals and Fertilizers
Government of India
Shastri Bhavan
New Delhi - 110001

Telex: 312755 mpc^f in
Telephone: 38 36 95

MEXICO Fermin FERNANDEZ-VIANA
General Coordinator
Ccmision Intersecretarial de la Industria
Farmaceutica
Ministry of Industries
Hermosillo 26
Mexico 06769, D.F.

Telex: 1775690

MOROCCO El Mokhtar FAZI
Président du Conseil National
de l'Ordre des Pharmaciens (CNOP)
287 Boulevard Liberté
Casablanca

Telephone: 27 15 75

NETHERLANDS J.W.C. MILDER
Gist Brocades N.V.
Industrial Division
Bulk Products
P.B.I. Wateringseweg 1
Delft

Telex: 38031 gbip nl

PAKISTAN F.R.Y. FAZLI
Chairman
Quality Control Authority
Ministry of Health
Government of Pakistan
Islamabad

Telex: SEHAT
Telephone: 29111

PERU

Gerard GARRIDO
Sintesis Quimica S.A. (SINQUISA)
Edificio Ejecutivo Pardo
Bolognesi 139
Lima 18

Telex: 20355 sinquisa

SPAIN

Francisco FERRANDIZ
Centro Desarrollo Tecnologico Industria (CDTI)
Ministerio de Industria y Energia
Edificio Gan
Calle Ramirez Arellano
Madrid

Telephone: 201 89 86

SWITZERLAND

Ernst B. VISCHER
Ciba-Geigy Ltd.
4002 Basel

Telex: 62991 cigy ch

UNITED STATES
OF AMERICA

Jan DLOUHY
Vice-President
Planning and Commercial Development
American Cyanamid Co.
1, Cyanamid Plaza
Wayne, N.J. 07410

Telephone: (201) 831 4027

O B S E R V E R S

FRANCE

Hervé BOLOT
Direction des Nations Unies
Ministère des Relations Extérieures
37 quai d'Orsay
75007 Paris

Telephone: 55 95 40

Jean TALARMIN
Services de Coopération et de Développement
Ministère des Relations Extérieures
20 rue Monsieur
75007 Paris

Telephone: 567 55 90

Gilberte SZWARCBERG
Syndicat National Industrie Pharmaceutique
88 rue de la Faisanderie
75016 Paris

Telephone: 503 21 01

Francis COUCELLE
SANOFI
37 Avenue Pierre Premier de Servie
75008 Paris

M. CERCEAU
Pharmacie Centrale des Hôpitaux de
l'Assistance Publique
7 rue de Fer à Moulin
Paris 5^{eme}

Telex: 204203 F

GREECE

Charalambos GOLEMIS
Head of Technical Unit
Price Research Council
22 Voulis Street
Athens

Telephone: 32 34 902 or
32 34 846

OCCGE

Dr. Cheick SOW
Secrétaire général
Organisation de coordination et de
coopération dans la lutte
contre les grandes endémies
Centre MURAZ
Bobo-Dirulatto
Haute Volta
Afrique de l'Ouest

Telephone: 900 47 (bureau)
995 79 (domicile)

ANNEXURE C

INDICATIVE LIST OF NON-CONFIDENTIAL REFERENCE INFORMATION REQUIRED
FOR CONDUCTING STUDY

1. Name of Product/Intermediate
2. Availability of Product/Intermediate
3. Chemical Flowsheet, non-confidential
4. Chemical Conversion Factors and/or Yields
5. Informative Prices of (Chemical) Inputs
6. Total Conversion Costs
 - Utilities)
 - Energy)
 - Salaries and Wages) upon developing countries' information
 - Depreciation)
 - Maintenance)
 - Overheads)
7. Fixed Capital Requirements; percentage of hard currency required;
local requirement
8. Minimum Economic Scale
9. Environmental Considerations
10. Labour Safety Regulations
11. Special Factors Affecting Present Process Economics (confidential)
12. Infrastructure Required
13. Skilled Personnel Required
14. Type of Technology Transfer (Joint Venture, Lump-Sum Arrangement,
Licensing)
15. In case of lump-sum arrangement, the extent to which the producer is
willing to provide assistance such as plant design information;
training, demonstration, etc.
16. Indication of any specific condition.

ANNEXURE D

Survey on availability of technology for the production of the 26 essential drugs included in UNIDO's list

<u>Essential Drugs</u>	<u>Developed Countries .</u>		<u>Developing Countries</u>
	<u>market economies</u>	<u>centrally planned economies</u>	
1. Acetylsalicylic acid	X		X
2. Ampicillin			X
3. Ascorbic acid			X
4. Chloroquine phosphate	X		X
5. Dapsone	X		X
6. Diethylcarbamazine	X	X	
7. Ethambutol		X	
8. Furosemide			X
9. Hydralazine	X		
10. Isoniazid		X	X
11. Mebendazole	X		
12. Paracetamol	X		X
13. Propranolol	X		
14. Reserpine	X		
15. Streptomycin			X
16. Sulfadimidine	X	X	X
17. Tetracycline	X		X
<u>Intermediates</u>			
a) D Phenyl Glycine		X	
b) 6 APA			X
<u>Number of replies</u>	7	1	6

Source: UNIDO survey.

