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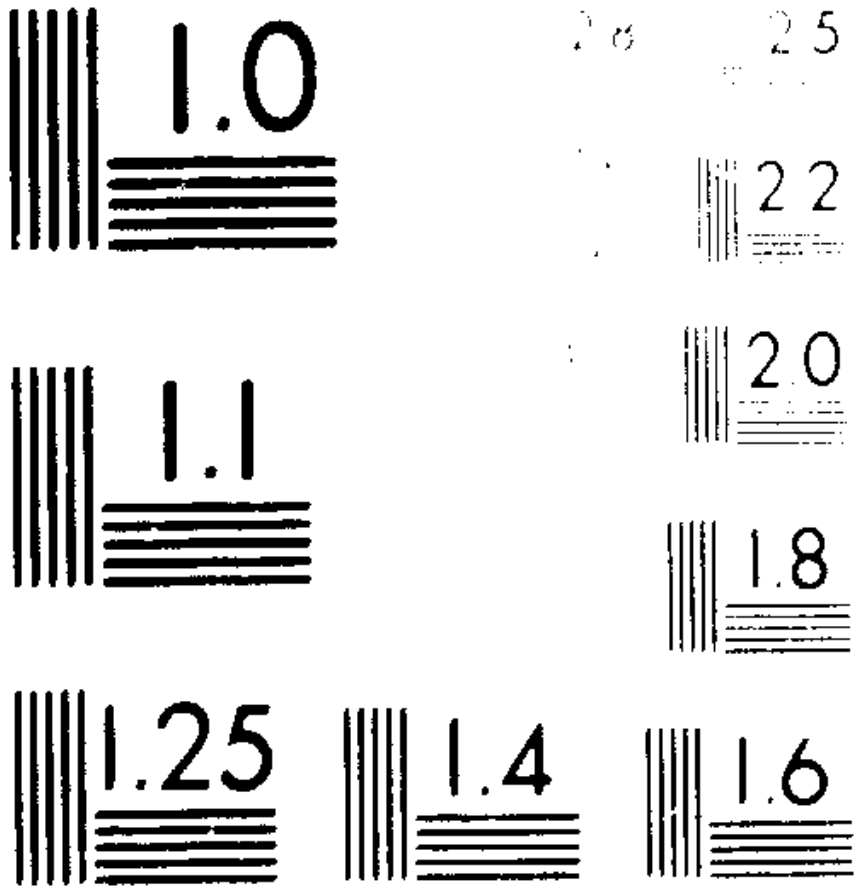
UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org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UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

15 December 1982

Division for Industrial Studies

Sectoral Studies Branch

Sector Study Methodology Meeting I

Vienna, 1-3 December 1982

12540

SUMMARY

OF THE PROCEEDINGS OF THE MEETING

Pam Barnacal
E. Meneses

This summary is for the restricted use of participants of the meeting.

SECTORAL STUDY METHODOLOGY MEETING I
Vienna, December 1-3, 1982

General framework and introduction to meeting

1. The First Sectoral Study Methodology Meeting was convened in the VIC, December 1-3, 1982. A suggested study programme for the pharmaceutical industry was the object of the discussions.

2. In the introduction to the meeting it was emphasized that it should concentrate on the methodology of the studies. It was further explained that this meeting was the first of a planned series and that meetings concerning the wood-processing industry and the capital goods industry would follow in 1983. The purpose of the present meeting was therefore twofold: The Secretariat sought concrete advice on the methodology for the sectoral studies in the pharmaceutical industry sector but also on how to organize and run methodology meetings in the future.

3. It was stressed that the meeting was purely informal and that all participants were invited in their personal capacity. Invited participants, UNIDO consultants and UNIDO staff participated in the meeting on equal terms.

4. UNIDO activities, particularly the System of Consultations, were described at the outset of the meeting. The way in which technical assistance, studies and the System of Consultation interact, mainly through the Task Force on Pharmaceutical Industry, was explained carefully. It was stressed repeatedly that the aim of the meeting was not to prepare for the Second Consultation but only to give advice on the study programme. It was also explained that it would only later be decided, through the Task Force, which of the suggested studies would actually be presented to the Consultation Meeting. It was further explained that the studies would have also other uses inside and outside UNIDO.

5. It was agreed by the participants that there would be no formal report on the meeting but that an oral summary and a critical evaluation of the discussions should be drafted by two consultants, participating in the meeting. These drafts should reflect their personal impressions and experience. The meeting also agreed to proceed, as suggested by the UNIDO

Secretariat, discussing the suggested study programme, study by study, following a background document entitled "Definitions, Outlines and Elements of Methodology in the Pharmaceutical Sector", which had been distributed in advance of the meeting.

6. This summary of the proceedings contains the following elements:

General framework for the suggested study programme in the pharmaceutical sector (Annex I).

Five study outlines presented by the Secretariat to the Meeting as basis for discussion (Annex II).

Further material presented by the Secretariat concerning data requirements, possible scenarios and overall time schedule (Annex III).

A summary report of the discussions at the meeting by a UNIDO consultant (Annex IV).

A critical evaluation of the discussions at the meeting by a UNIDO consultant (Annex V).

A list of participants (Annex VI).

7. This material is presented only to the participants in the meeting and to interested parties within the UNIDO Secretariat. It is presented for information only and does not entail any acceptance of the views presented in the consultants' papers by the UNIDO Secrtariat as a whole or by the Sectoral Studies Branch. The comments made during the discussions will, however, be guiding the future work on the study programme.

8. The Sectoral Studies Branch expresses its warm gratitude to the participants, the consultants and colleagues from sister branches within the Secretariat who all contributed to a very constructive and extremely useful discussion.

ANNEX I

General Framework for the suggested Study Programme in the Pharmaceutical Sector

A Schematic Illustration

1. GENERAL OBJECTIVES
   - 1.1 Global overview
   - 1.2 Focus on developing countries
   - 1.3 Identification of problem areas for detailed analysis.
2. SCOPE
   - 2.1 Established priorities
     - 2.1.1 Issues identified by the First Consultation
       - (a) availability and pricing of pharmaceutical bulk substances and their intermediates;
       - (b) contractual arrangements;
       - (c) transfer of technology for the 26 essential drugs identified in the UNIDO/WHO Illustrative List of 26 Essential Drugs.
     - 2.1.2 UNIDO Selection of Drugs for Local Production in Developing Countries
       - (a) 9 priority drugs;
       - (b) 26 essential drugs.
   - 2.2 Possible Extension of the Production Programme
     - 2.2.1 Technological considerations based on the similarity of the production resources.
     - 2.2.2 Economic considerations to achieve overall feasibility of the potential investment.
3. METHODOLOGY
   - 3.1 The pharmaceutical industry is seen as a component of the health, industrial and economic development process.
   - 3.2 Identification of technical or scientific problems, subsequent economic analysis of technical alternatives.
   - 3.3 Analysis of the socio-political acceptance.
   - 3.4 Source and reliability of data.
   - 3.5 Available resources (funds, staff, consultants, etc.).
   - 3.6 Time constraints.

ANNEX II

Study Outlines:

Technoeconomic Analysis of the WHO Revised Model List of Essential Drugs as a Guideline for the Selection of Production Programmes

Production of Immunizing Agents and Diagnostic Antigens in Developing Countries

Some Aspects of Research and Development Activities in the Pharmaceutical Sector

Global Scenarios by the Years 1990 and 2000 in the Pharmaceutical Industries in Developing Countries

Second World-wide Study on the Pharmaceutical Industry

ANNEX II

Study on the "Technoeconomic Analysis of the WHO Revised Model List of Essential Drugs as a Guideline for the Selection of Production Programmes"

Suggested Structuring

1. OBJECTIVE

To assist developing countries in the selection of drugs for local production in the three subsectors.

2. SCOPE

Subsector I: 26 essential drugs

Subsector II: 9 priority drugs

Subsector III: biologicals used in the prevention of diseases in the WHO Expanded Programme of Immunization.

3. METHODOLOGY

3.1 Subsector I: Pharmaceutical dosage forms of the 26 essential drugs

3.2 Technical analysis: The 26 essential drugs in the UNIDO/WHO Illustrative List represent 57 dosage forms in the following classification:

22 compressed tablets
9 coated compressed tablets or capsules
18 injections (of different kinds)
5 elixirs, syrups and oral suspensions
3 suppositories

Some identified problems are:

(a) Should capsules or film-coated tablets be given priority?

(b) Dosage form priority for local production should it be decided on the basis of complexity of methods of manufacture or economic grounds or both?

(c) What is the optimum retail and hospital packing for every item?

(d) Could standard technologies be useful (proven bio-equivalence, stability and absence of technical problems during processing)?

(e) Would comparison of cif prices and cost estimates (neglecting local factors, such as duty, clearing charges, etc.) be useful?

(f) Should generics be given priority in developing countries?

3.3 Subsector II:

Methodology for the Technoeconomic Analysis of the Manufacture of Pharmaceutical Bulk Substances produced by Organic Chemical Synthesis

(Please refer to the background paper, pp. 16-22)

The same approach can be used for 7 of the 9 priority pharmaceutical bulk substances, actually for all chemicals, produced by organic synthesis.

A separate method should be elaborated for pharmaceutical bulk substances produced by biotechnology, mainly fermentation.

3.4 Subsector III: A separate study titled "Production of Immunizing Agents and Diagnostic Antigens in Developing Countries" deals with this subject.

Sectoral Studies Branch 21 June 1982

DRAFT OUTLINE OF THE STUDY "PRODUCTION OF IMMUNIZING AGENTS AND DIAGNOSTIC ANTIGENS IN DEVELOPING COUNTRIES"

1. BACKGROUND AND OBJECTIVES

The extension of the immunization programme to the whole population is a major public health problem in developing countries. One person's treatment or lack of treatment will directly affect the likelihood of other people in the community becoming ill.

The developing countries, as a group, constitute large markets for prophylactic drugs which are manufactured primarily in industrialized countries. On the other hand, there are special factors that favour local production, e.g. vaccines and sera should be stored at a temperature below 5° sometimes at -20° also during shipment. The shortest expiration date is 30 days but 1 year is not an unusual period.

Technology and training facilities are available from various sources inclusive developing countries. Production plants can be set up with a relatively small investment on a turnkey basis.

The overall objective is to help developing countries achieving the goal of "Health for all by the year 2000" as defined by WHO.

The industrial objective is to assist developing countries to establish local production of immunological preparations in order to replace imports from industrialized countries.

2. ECONOMIC ANALYSIS

Comparison of the benefits and costs of the local production of immunizing agents and vaccination programmes taking into account both industrial criteria, such as the value added content, investment costs, costs of production and R & D, and socio-economic factors, such as the improvement of infant mortality, premature deaths, averted treatment costs, etc.

(5 pages)

3. PRODUCTION AND MARKETS

Appraisal of the present situation as well as analysis of 1990/2000 scenarios for the global production and markets of sero-bacteriological preparations, with special emphasis on the six infectious diseases:

- diphtheria,
- measles,
- pertussis,
- poliomyelitis,
- tetanus, and
- tuberculosis,

identified as first priorities in the Expanded Programme on Immunization by WHO.

Other diseases therapeutically important in developing countries to be analysed:

- cholera,
- influenza,
- meningitis,
- rabies,
- rubella,
- typhoid and paratyphoid infections,
- yellow fever,

and the particular case of snake bites.

Production of diagnostics associated with the above diseases.

Potential inclusion of immunoglobulins, plasma fractions, plasma substitutes and parenteral infusions in the production programme.

Potential inclusions of veterinary vaccines in the production programme. (40 pages)

4. PROCESS ECONOMICS

A simple description of the production processes of BCG Vaccine, Pertussis Vaccine, Diphtheria Toxoid, Tetanus Toxoid, Diphtheria and Tetanus Toxoids and Pertussis Vaccine combined, Measles Virus Vaccine Live, Poliovirus Vaccine Live Oral, Diphtheria Antitoxin, Tetanus Antitoxin and Tuberculin with technical difficulties encountered in manufacturing; description of the plant and equipment inclusive the quality control department; informative production and investment costs..

Patent situation. (40 Pages)

5. RESEARCH AND DEVELOPMENT

5.1 Processes

New technologies, notably genetic engineering, that might affect production economics over the next 10-20 years.

5.2 Products

New products should be classified into three categories:

(a) most likely to be commercialized before 1990;

(b) preliminary experimental evidence suggests that a useful vaccine can be produced;

(c) more hypothetic group, such as vaccines against malaria, parasites, cancer, etc. and gene preparations, e.g., in the treatment of sickle-cell anaemia. (20 pages)

6. INTERNATIONAL CO-OPERATION

Identification of potential sources of technology.

Co-operation among developing countries. (5 pages)

7. CONCLUSIONS AND RECOMMENDATIONS

To be given as a result of the study. (5 pages)

Sectoral Studies Branch

JAP/ri

25 November 1982

SOME ASPECTS OF RESEARCH AND DEVELOPMENT ACTIVITIES IN THE PHARMACEUTICAL SECTOR

DRAFT OUTLINE

1. OBJECTIVES

The industrial objective is to assist developing countries in the selection of applied research programmes that (a) assure the good quality of drugs, and (b) upgrade the economic efficieny of the manufacturing processes used in the local production of these drugs.

The overall objective is to analyse the possible impact of new scientific and technical discoveries that might affect the pharmaceutical sector, paying special attention to both the diseases for which no satisfactory therapy exists and the process of industrialization in developing countries.

2. BACKGROUND AND SOME ECONOMIC ASPECTS OF RESEARCH AND DEVELOPMENT

Pure basic research. Discovery research. Applied research. Development. The innovative process. The necessity for R + D. R + D as an investment. Orphan drugs.

3. RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL SECTOR

Research for new drugs (new chemical entities). Stages in the discovery and development of a typical drug. Time table and cost estimate of R + D. Present status and constraints of conducting R + D activities in developing countries. New therapeutic breakthrough products.

3.1 R + D in the Pharmaceutical Dosage Form Subsector

Applied research related to the health registration of licensed and generic drug preparations. Pharmaceuticals in the "UNIDO/WHO Illustrative List of 26 Essential Drugs" presenting actual or potential bioequivalence problems. Elaboration of standard dosage form processing technologies. Technological breakthroughs that might affect the quality or the economics of medical treatment, such as lowering the single dose through increased bioavailability or improving the side-effect profile of a drug through controlled-release dosage forms.

3.2 R + D in the Pharmaceutical Bulk Substance Subsector

Process research related to the manufacture of pharmaceutical bulk substances in the "UNIDO/WHO Illustrative List of 26 Essential Drugs" including process research of their chemical intermediates with limited availability on the world market.

Preparation of bulk substances with optimized physical properties for the manufacture of dosage forms, e.g. directly compressible grade of acetylsalicyclic acid, chloroquine phosphate and paracetamol bulk substances for tableting.

Possible impacts of genetic manipulation on the process efficiency of pharmaceuticals with proven value, such as gentamicin, penicillin and insulin and new chemical entities, e.g. interferons, polypeptide hormones, etc.

3.3. R + D in the Biological Preparations Subsector

Possible impacts of process research on biological preparations related to the WHO Expanded Programme on Immunization.

New technologies that might affect production economics or result in new products with special relevance to developing countries, such as vaccines against malaria, parasites, etc.

4. SOME INTERNATIONAL ASPECTS OF PHARMACEUTICAL R + D

The international character of pharmaceutical R + D. Sources of information on R + D in the pharmaceutical sector.

5. CONCLUSIONS AND RECOMMENDATIONS

To be drawn on the basis of findings.

Sectoral Studies Branch JAP/ri

29 November 1982

GLOBAL SCENARIOS BY THE YEARS 1990 AND 2000 IN THE PHARMACEUTICAL INDUSTRIES IN DEVELOPING COUNTRIES

1. BACKGROUND AND OBJECTIVES

The Lima Declaration and Plan of Action on Industrial Development and Cooperation, adopted by the Second General Conference of UNIDO in 1975, specified the need for a better balance in the structure of world production. It set the goal of an increase in the share of the developing countries in total world industrial production from 7% to at least 25% by the year 2000.

The overall objective of this study is to establish a selected set of indicators to measure the industrial status of the pharmaceutical sector that will enable decision-makers to assess the effectiveness and efficiency of indigenous industrial policies in the light of the Lima Declaration and Plan of Action.

The industrial objective is to estimate the demand for pharmaceuticals by the years 1990 and 2000 on the basis of both extrapolating present trends and assuming different degrees of improved health care in developing countries.

2. INDICATORS TO ASSESS THE STATUS QUO AND 1990 AND 2000 PROSPECTS IN THE PHARMACEUTICAL SECTOR

2.1 General Indicators

Demographic changes relevant to the sector. GNP per capital by continents and regions.

2.2 Health Indicators

"All-causes" mortality, infant mortality and life-expectancy at birth. Specific mortality and morbidity statistics with special emphasis on diseases prevailing in developing countries. Health resources: expenditure on health and drugs, facilities and manpower.

2.3 Pharma-Industrial Indicators

National statistical data for pharmaceutical production, trade and consumption on subsectoral level might include the following indicators:

- production/ex-factory total value, number of establishments, ownership structure, market share
- imports/c.i.f. value
- exports/f.o.b. value
- R + D facilities (number of government institutes and companies engaged in local research, namely: new chemical entities, new chemcial fermentation and pharmaceutical technological processes, animal pharmacology and toxicology, clinical pharmacology).
- product information (production, imports and exports) on pharmaceuticals in the "UNIDO/WHO Illustrative List of 26 Essential Drugs" and on the biological products required for the implementation of the "Expanded Progrmme of Immunization" of WHO.
- planned projects (same data as for production above).

Only when these data are available will it be possible to discern regional global trends.

3. 1990 AND 2000 GLOBAL SCENARIOS BASED ON 1980 PHARMACEUTICAL SALES

Analysis of the global and continental markets: total values and market growth assuming that (a) drugs are available for 20% to 50% of the population in developing countries at present, and (b) this coverage will grow proportionally with increase in GNP per capita and changes in demographic data.

Qualitative analysis of drug demand in the light of changing mortality and morbidity patterns.

Changes in demand for pharmaceuticals in the "UNIDO/WHO Illustrative List of 26 Essential Drugs" and for biological products required for the implementation of the "Expanded Programme on Immunization" of WHO.

Some features of R + D that might affect 1990 and 2000 demand for drugs in developing countries.

Analysis of industrial development factors that depend primarily on international cooperation.

4. CONCLUSIONS AND RECOMMENDATIONS

Based on the findings of the study alternative subsectoral strategies will be proposed for (groups of) developing countries.

Sectoral Studies Branch
Division for Industrial Studies

12 May 1982
J. Pogány

SECOND WORLD-WIDE STUDY ON THE PHARMACEUTICAL INDUSTRY

Second Draft Outline

1. OBJECTIVES OF THE STUDY AND CHARACTERISTICS OF THE SECTOR

1.1 Objectives of the study

Proposed way of establishing pharmaceutical industry in developing countries in accordance with the principles of The Lima Declaration and Plan of Action as well as the conclusions and recommendations of the First Consultation.

1.2 Broad presentation of the sector and its subsectors

Classification of production and trade.

1.3 Overall characteristics and special features of the sector

Importance of the sector in the world economy and national economies. Technical and economic characteristics of the pharmaceutical industry and drug markets.

1.4 Interlinkages with other sectors

Industries affecting the production of drugs in developing countries, such as chemical, glass, paper, plastic and printing industries. Impact on the development of other sectors.

2. GLOBAL OVERVIEW OF THE SECTOR

2.1 Consumption and demand

Global, regional and national analysis of imports, domestic sales, exports and demand based on market information and health statistics.

2.2 Production

Status of the industry in developing countries in the context of the world-wide situation. Analysis of the main trends affecting the industry, such as capital, profitability, R+D, manpower, etc.

3. MAJOR CONSTRAINTS AFFECTING THE ESTABLISHMENT OF PHARMACEUTICAL INDUSTRY IN DEVELOPING COUNTRIES

3.1 Factors depending primarily on developing countries

Coordinated national policies (industrial, health, trade, planning and education of professionals), drug budgets, national health insurance schemes, investment climate, satisfactory information on national drug markets, export promotion, etc.

3.2 Factors depending primarily on industrialized countries

Availability of technical and marketing know-how, research and development background, training of manpower.

4. ISSUES IDENTIFIED BY THE FIRST CONSULTATION

4.1 Availability of active substances and intermediates

Analysis of the technical and economical aspects of the availability of active substances and intermediates of the 26 priority drugs included in the UNIDO list.

4.2 Contractual arrangements

Various terms and conditions for the establishment of plants in developing countries for the production of pharmaceutical dosage forms and active substances as well as necessary intermediates.

4.3 Transfer of technology

Mutually acceptable and equitable terms and conditions on which technology can be supplied to developing countries for the local production of essential drugs.

5. PROSPECTS OF THE SECTOR BY 1990 AND 2000. SCENARIOS. ALTERNATIVE STRATEGIES

5.1 Global and regional projection of the demand and production to the years 1990 and 2000

Future of the pharmaceutical industry in developing countries based on present market trends and socio-economic changes.

5.2 Scenario analysis

Different scenarios based on "normative" and "business as usual" and "crisis" assumptions.

5.3 Alternative strategies

Analysis of strategies applicable to (groups of) developing countries, paying special attention to the least developed countries, such as co-operation with industrialized countries, co-operation among developing countries, establishment of own R+D facilities.

6. CONCLUSIONS AND RECOMMENDATIONS

(to be specified)

ANNEXES

BIBLIOGRAPHY

ANNEX III

Material presented by the Secretariat concerning possible scenarios, data requirements and overall time schedule

Level of industrialization in the year 2000	"Lima - secenarios"		"Historic trends"	
Co-operation strategy / "Pharmaceutical targets"	North-South co-operation	South-South preferred	North-South co-operation	South-South preferred
Moderate increase in drug availability in developing countries	Impact and consequences on: A. Health in developing countries B. Pharmaceutical industry in developing countries Demand Production Production, distribution of Investment requirements Financing requirements Manpower requirements Technological development Trade C. Industrialization and Development in general			
Normative (=strong increase) in drug availability in developing countries				

DATA REQUIREMENTS

VARIABLES	USED FOR
A. Economic and Health Statistics	Whole Study programme
B. Pharmaceutical Industry Time series 1970 onwards - Production - Int. trade - Dedicated plants	General UNIDO data base on the pharmaceutical industry
C. 9 + 26 drugs Time series 1970 onwards - Production - Int. trade - Prices (Index of changes only?)	

AVAILABILITY

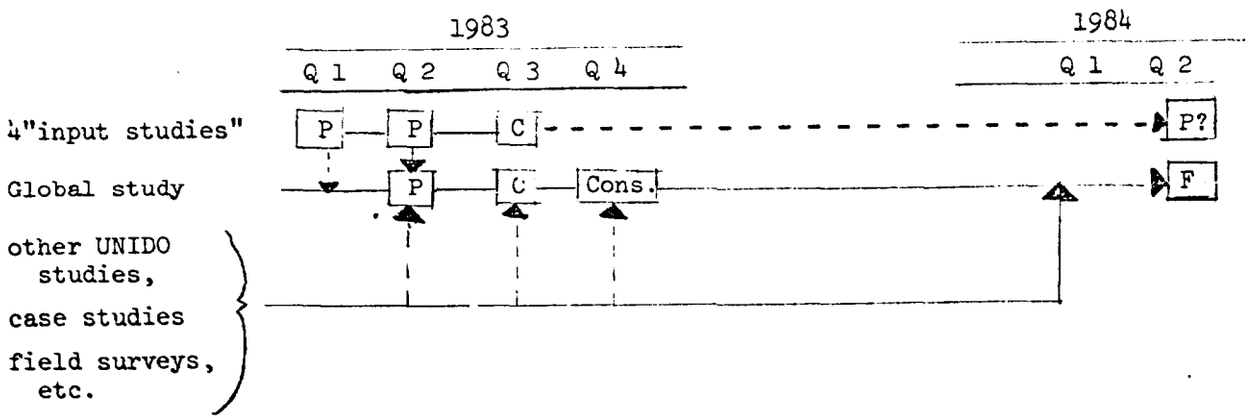
Ind. Countries	Dev. Countries
Easily available in international statistics (UN, UNIDO, WHO)	
ISIC 3522 national statistics only?	
SITC 54	
National stats?	National stats?
Industrial associations?	Collection through national agencies
Consumption data from d.c.'s.	Field Surveys
Ad hoc info. SCRIP, etc.	Export stats from industrialized countries.

DATA REQUIREMENTS

VARIABLES	USED FOR
D. Technological data	Technoeconomic study
Paris list of non-confidential reference information.	R + D Study
1. Name of product	Evaluation of technology transfer as part of T.A. (not under discussion here)
2. Availability of product	
3. Chemical Flowsheet	
4. Chemical conversion factors	
5. Prices of chem. inputs	
6. Conversion costs	
7. Fixed Capital Requirements	
8. Minimum Economic Scale	
9. Environmental Considerations	
10. Labour Safety Regulations	
11. Special Factors	
12. Infrastructure Required	
13. Skilled Personnel Required	
14. Type of Technology Transfer	
15. In case of lump-sum arrangement, extent of assistance	
16. Specific conditions	

AVAILABILITY	
Ind. Countries	Dev. Countries
Literature	Commercial scale data available from national agencies, where such data exist
Text books	
Patents	
UNIDO studies	
Industrial sources	

Overall Time Schedule



P = Preliminary (internal) drafts (not necessarily whole study)

C = Circulation draft (complete study)

F = Final study (revised and supplemented; possibly sales publication)

ANNEX IV

8 December 1982

SUMMARY REPORT ON

Sectoral Study Methodology Meeting I

Vienna, 1-3 December 1982

by

Pam Barnacal, Consultant to the UNIDO Secretariat

A. INTRODUCTION

This report attempts to summarize the discussions which took place at the Sectoral Study Methodology Meeting I held in Vienna on December 1st-3rd, 1982. Divided into seven parts, the report first covers the six major topics discussed at the meeting (classification of industries, etc. and the five main studies presented) and then looks at some of the general comments/recommendations on overall methodology which emerged from the meeting. For each of the six major topics discussed, a brief summary of the objectives and outline of the study is first given in order to put the comments of participants into perspective. The final section on general comments/recommendations regarding the meeting puts special emphasis on the collection of data since this was seen as being fundamental to the success of UNIDO sectoral studies.

B. CLASSIFICATION OF THE INDUSTRY

It was pointed out in the background (working) paper that the classification of drugs for UNIDO purposes (local production in developing countries) was more difficult than for WHO purposes (selection of essential drugs for developing countries) in that the UNIDO classification must take into account:

1. the variety of inputs/outputs;
2. the production processes involved; and
3. the availability of technology (off- or on-patent)

1. Production processes: Drugs were classified into 7 groups depending on their method of manufacture.
   Subsectors: Applying this classification to the WHO essential drug list resulted in 3 main subsectors:
   - pharmaceutical preparations
   - pharmaceutical bulk substances
   - biological preparations

2. Inputs/Outputs: These were classified into four categories for which definitions and examples were provided:
   - commodity chemicals
   - pseudo-commodity chemicals
   - fine chemicals
   - specialty chemicals

   Each of the four categories could then be described in terms of a number of parameters such as:
   availability, level of technology, pricing, end-users.

3. Technology: In order to classify finished drugs in terms of the availability of technology (mainly on- or off-patent) and marketing technique, four categories were defined:
   - commodity generics
   - differentiated generics

- pseudo-generics
- original new drugs

Comments:

According to Mr. Pogany. the objectives of the classification were to:

(i) identify products in a form suitable for production programmes

(ii) for possible inclusion in UN statistics to facilitate data collection.

Questions were raised as to under which categories particular drugs would fall:

e.g. - was chlorpromazine a fine chemical or a specialty chemical
- how would off-patent drugs with product exclusivity be classified.

It was suggested that a classification by the number of sellers and buyers would provide an alternative method of evaluating factors such as availability, pricing (competitive, oligopolistic or monopolistic) competition, market share, etc.

The proposed classification could have wider implications as a decision-making tool, i.e. not just limited to the WHO essential drug list.

Market exclusivity was highlighted as an important factor and a separate list could be prepared for "problem" intermediates.

A "dynamic" element, such as price trends could be incorporated into the classification (although the problems of obtaining pricing information were also mentioned).

When assessing finished drugs in terms of whether they were on- or off-patent, both product and process patents should be observed.

C. TECHNO-ECONOMIC ANALYSIS

The objective of the study is to assist developing countries in the selection of drugs for local production.

The study outline covered:

1) Principal criteria for the selection of drugs - health, techno-economic and sociopolitical.
2) Established priorities such as: the UNIDO illustrative list of 26 essential drugs, the WHO model list of essential drugs and the 9 priority drugs and their intermediates selected by UNIDO;
3) Methodology for the selection of drugs in terms of the established priorities above.
4) Methodology in terms of a techno-economic analysis using chloroquine synthesis as an example. The analysis was broken down into four parts:

   (i) schematic illustration of the synthesis;
   (ii) chemical reactions;
   (iii) chemical conversion factors
   (iv) impact of intermediate prices on production costs.

Much of the discussion centred on this techno-economic analysis, particularly in terms of

(i) its validity in assessing the efficiency of a production process; and
(ii) the validity of the prices used.

Comments

Comments from the participants tended to fall into two schools of thought:

1) Those who had used the technique in production analyses and had found it useful. Also those who regarded the analysis as a practical tool for deciding

   (i) whether a bulk drug should be imported or produced locally, and
   (ii) whether or not the offer of a specific technology represented value for money.

2) Those who regarded the analysis as being too simplistic and based on arbitrary values.

Certain participants who were not familiar with this approach found it too theoretical. Linked to this was the question of to whom the study was addressed: non-technical readers could encounter similar problems.

The analysis, it was suggested, was too theoretical for the decision-maker and too simplistic for the production manager. Feasibility studies still had to be conducted and the efficiency of a production process or technology could only be assessed once the process had been carried out in a plant. Therefore what was its real value? Perhaps the analysis should be regarded as the last, rather than the first step in the assessment of a production process.

The "top-down" approach could be used as an alternative method.

The relation between input and output could be studied by using a simple computer model. UNIDO could develop software for the evaluation of technology and this software programme could then be purchased by developing countries.

Rather than a single "spot" price, price ranges and historical pricing trends should be taken into account. The subject of transfer pricing was raised and it was suggested that high import prices were favourable as far as competition with locally-produced drugs was concerned.

The importance of "software" (R + D, marketing, the healthcare system, distribution, etc.) was stressed since this was linked to profitability and pricing. For example, a company may be able to produce a drug but it may not be able to sell it. Costs of manpower, storage facilities, etc. varied from country to country, and an efficient technology in an industrialized country may not be so efficient in a developing country. Thus, it would be useful to collect data on the "software" of a given country.

With regard to methodology, case-studies could make a useful contribution. In the developing countries, these could examine how decisions had been made in the past and what lessons could be learnt from past experience. In the developed countries, case-studies could look at how problems of cost-efficiency were overcome and whether the observed patterns could be extrapolated to developing countries.

A clear distinction should be made between bulk drugs and finished drugs. For finished drugs, factors such as GMP, quality control, software and marketing were more important than for bulk drugs.

D. PRODUCTION OF IMMUNIZING AGENTS/DIAGNOSTIC ANTIGENS

The objective of the study is to assist developing countries in establishing local production of immunological preparations in order to replace imports.

The study outline covered:

- the benefits and costs of local production
- production and consumption primarily in terms of the WHO/EPI programme (i.e. the six diseases specified)
- production in terms of processes available, equipment required and investment costs;
- R + D in terms of new process technology and new products which could have an impact over the next 10-20 years, particularly with regard to biotechnology;
- international cooperation in terms of source of supply and TCDC.

Comments

The study should stress the importance of local production of immunizing agents in terms of the saving of foreign currency, advantages of preventive medicine, the relatively low level of investment required and the availability of technology.

The cost-effectiveness of immunization programmes should be emphasized in terms of the saving in treatment costs that can be achieved by preventive therapy.

Immunization programmes represent an area where UNIDO activities overlap with those of the WHO. It was suggested that any duplication of effort between WHO and UNIDO should be avcided. The study must clarifiy where UNIDO's responsibility ends and the WHO's starts. Is UNIDO's role limited purely to local production of immunizing agents, or does it also cover local infrastructure to ensure the success of national immunization programmes?

The study must stress the importance of economies of scale for vaccine production. One participant referred to a paper by Frank Perkins of WHO which indicated that for a population of 20 million with a birth rate of 30 per 1000, total annual requirements would be two batches of polio (oral), BCG and measles, and four batches of DPT. This puts economies of scale in perspective. For certain countries (developed and developing) local production is not always economically feasible: on the other hand, several developed countries are prepared to sacrifice economies of scale for security of supply, for example in the event of a national epidemic.

Alternative strategies to national production should be considered such as regional cooperation or the limitation of national production to "filling" only. It was suggested that developing countries' involvement in local production could be viewed at three levels:

1. quality control;
2. filling of diluted concentrate; and
3. basic production.

It was pointed out that certain companies in industrialized countries had ceased production of vaccines because it was not profitable. The study should therefore look at world supply aspects. In this context, it could also be mentioned that in most developed countries, governments are reluctant to rely on foreign companies for supply of vaccines and, wherever possible, vaccine production is in the hands of the public rather than the private sector (e.g. Connaught in Canada, Commonwealth Serum Laboratories in Australia, Institut Pasteur in France) so as to guarantee sources of supply.

Technology for vaccine production can become outdated very quickly. This is particularly relevant here as current research in biotechnology is expected to bring about some major innovations in terms of both products and processes over the next 10-20 years. The study should examine:

1. what are the current needs of the developing countries?

2. how can these needs be met by currently available technology?
3. where gaps exist between needs and technology, how can they best be filled?
4. what major innovations can be expected in the future? and
5. what are the incentives for companies to supply this new technology to developing countries.

Several participants referred to the importance, in this context, of the infrastructure available, i.e. distribution, health care personnel, vaccination/public health campaigns. Again, is this the responsibility of UNIDO or WHO?

The "case-study" methodology was again proposed at two levels:

1. developed countries - what are the economies of scale involved? and
2. developing countries- which countries undertake local manufacture, what problems are encountered and why have immunization programmes failed in the past?

E. RESEARCH AND DEVELOPMENT

The objective of this study is to assist developing countries in the selection of applied research programmes and to assess the impact of new discoveries in the pharmaceutical sector, particularly with regard to diseases for which no satisfactory therapy exists.

The scope of the study covers:

1. Economic aspects of R + D;
2. R + D in the pharmaceutical sector
   - dosage forms (formulation of 26 essential drugs)
   - bulk substances (process development for 9 intermediates)
   - biological preparations
3. International aspects of pharmaceutical R + D.

Comments

The study should outline the different types of research undertaken in the pharmaceutical sector and the costs of each type.

The cost of innovative research (i.e. development of new chemical entities) is becoming prohibitive for many pharmaceutical companies in industrialized countries, let alone the developing countries.

The study must therefore concentrate on how the resources of the developing countries (personnel, facilities and finance) can best be deployed to meet their own real needs. Priority areas of R + D open to developing countries include: the development of production processes; clinical research; and the development of dosage forms to meet local social and environmental conditions.

The R + D of new chemical entities to treat diseases for which no therapy is currently available is a real problem: the developing countries have neither the funds nor the resources, and there is little profit incentive for multinational companies. The study must address this problem by examining the alternatives available: if responsibility lies in the private sector, are

incentives needed and, if so, what incentives are available? If responsibility lies in the public sector, how can it be funded? Is there a role for cooperation between the two sectors? Do the governments of developed countries have a part to play in providing funds in the form of aid? How can developing countries attract the type of research conducted in the laboratories of multinational companies?

The registration requirements presented were considered to be too complicated: they should, it was suggested, be limited to tests to guarantee the quality of locally produced pharmaceutical preparations, particularly bio-equivalence and stability.

F. GLOBAL SCENARIOS

According to the study outline, the objective of this study was to establish a set of indicators to measure the industrial status of the pharmaceutical sector and (in the longer term) to enable progress towards the Lima target to be evaluated.

the discussion centred on three main aspects:

1. assumptions on which to base the scenarios;
2. the establishment of a fundamental set of indicators as stated in the objective above;
3. the collection of data.

Assumptions

Mr. Karlsson presented a number of scenarios based on the following assumptions:

1. cooperation strategy (North-South cooperation, South-South preferred in terms of the Lima target and historic trends);
2. pharmaceutical targets (moderate and normative increase in drug availability in developing countries).

This resulted in 8 scenarios whereas a maximum of three could be undertaken.

Mr. von Haunalter presented an outline of how a scenario study could be undertaken in terms of objectives, scope and methodology. Growth determinants were listed in terms of price (e.g. reimbursement, inflation, etc.) and unit influences (marketing tactics, disease incidence, demographics, etc.). Other assumptions suggested were:

1. attainment of the WHO target worldwide; or
2. only 25% access to primary health care.

It was generally agreed that scenario studies would prove very useful but they were difficult to undertake, particularly on a global scale. Alternatives suggested included:

1. regional scenarios;
2. scenarios based on a "sample", e.g. a population of 30,000 or the population served by a healthcare unit such as a hospital;
3. a number of national scenarios;
4. mention was made of the IDMA scenario study on the situation in India and this could prove useful in assessing how UNIDO should undertake scenario studies.

Set of Indicators

The minimum set of indicators required for a scenario analysis were identified as:

production, imports, exports, R + D facilities, consumption and production information.

Comments included the following:

- there is generally a good correlation between GNP/GDP and pharmaceutical expenditure. The problem was how to forecast GDP/GNP.
- the social security system (drug reimbursement scheme) and its coverage of the population should be taken into account.
- the extent of birth control and its impact on demographic trends should be considered.

Collection of Data

No matter what methodology is used, the success of a scenario study lies in having access to data on which the scenarios are to be based. This aspect was discussed extensively with regard to:

1. availability from developed and developing countries; and
2. the nature of the data itself - confidential versus non-confidential, economic/health versus technological, and general versus product-specific.

Mr. Karlsson later presented a table summarizing the data requirements and also an overall time-scale to indicate the time constraints on the scenario study as well as the other studies. Other comments made by participants included:

- even where UN statistics are available, they are not always comparable on an intercountry basis;
- requests for data should be realistic and neither IMS nor pharmaceutical companies could be expected to divulge "confidential" data. This did not mean that pharmaceutical companies could not be approached for non-confidential data such as location of manufacturing plants and R + D facilities;
- in general, developing countries were more willing to supply information on pricing, the cost of technology, etc. which developed countries tended to treat as confidential;
- certain participants offered to assist UNIDO in the collection of data and these should be followed up.

G. SECOND GLOBAL STUDY

Comments

It was noted that the first global study provoked a good deal of controversy at the First Consultation, particularly from industrialized countries who criticised the study on three main grounds: inaccuracies, bias and "overall tone". The proposed timetable whereby a circulation draft would be presented at the Second Consultation and a final draft would take into account observations made at the consultation would avoid this problem of controversy. Certain participants, however, questioned whether there was a real need to incorporate the comments made at the Second Consultation into the actual study and suggested that it might be sufficient simply to include the comments as an addendum or annexe.

Questions were raised as to the relationship between the first and second global studies: would the second study take into account tasks proposed at the First Consultation? To what extent could the second study be regarded as an updating of the first study or should it be regarded as a completely new study? The first study was a background paper whereas, since the outline of the second study contained a section on recommendations and conclusions, should it be regarded as a discussion paper?

The second global study should include a simple classification of all developing countries according to the stage of pharmaceutical manufacture which they have reached. This would be relatively simple to prepare and would provide an easy reference to put the range of developing countries involved into perspective.

The study should examine technical and marketing characteristics of the pharmaceutical industry, particularly with regard to the level of regulation in each country since this has implications for transfer of technology and exports.

The study should stress that it is important to link a country's national drug policy to its industrial policy. The example was given of plants

established in Latin America in the 1940s which were subsequently closed down, first because they were not economically viable because of low-yield strains but also because of the government's pricing policy at the time.

The study should analyse the role of the public sector and the resources for investment available to developing countries.

The first global study included a lot of valuable data on production of medicinal plants in the developing countries. This should also be taken into account in the second study.

Within the range of developing countries, the least developed countries could learn a lot from the experience of more developed countries such as India, Brazil, Egypt. The study should include country case-studies which could take the form of a chronology: when was a decision made to start local manufacture of finished drugs? How long did it take to achieve a certain level of local production? When and why were public sector companies set up and do they serve their purpose? Why is India so advanced, while Nigeria is lagging behind in terms of pharmaceutical manufacture?

The study should review the existing operations of multinational companies (MNCs) in developing countries, both in terms of negative aspects (e.g. allegations of inducing drug shortages or excessive promotion or closure of plants) and positive aspects (e.g. the conduct of R + D in cooperation with developing countries). Linked to this is the question of how governments control the activities of MNCs through government regulation, e.g. pricing policies or reduction of foreign equity, etc.

The study should point out that not all developing countries should be expected to go through each stage of backward integration to the manufacture of basic drugs: in some cases, optimum efficiency and cost-effectiveness might be achieved at the first stage of local production of formulations from imported basic drugs.

Although UNIDO is primarily concerned with the Lima target, it should not be blinkered to this one outlook and should take into account other factors such as infrastructure to put the real priorities in perspective. The example was quoted of India which is regarded as having an advanced pharmaceutical industry and yet only 25% of the population has access to modern drugs.

The study should stress the importance of population control in the economic and industrial development of a country. It was suggested that a country like Thailand which had introduced family planning programmes on a wide scale was in a far better position to make economic progress than a country where the population was left unchecked.

If the developed countries are to assist the developing countries, then the developing countries' expectations should be realistic. For example, the transfer of technology at royalty rates of 0-3% was an unrealistic approach: transfer of technology should be seen to take place on a practical rather than on a political level. Whether it be R + D or transfer of technology, there must be some incentive for the developed countries to assist the developing countries.

H. GENERAL COMMENTS/RECOMMENDATIONS ON THE MEETING

Future meetings should attempt to ensure participation by representatives of developing countries. At this meeting, only two of the seven participants was from a developing country.

It would be helpful if the studies were circulated well ahead of the meeting to allow sufficient time to analyse them more thoroughly.

The discussion sometimes impinged on subjects which might also come under the remit of other UN agencies, notably WHO and UNCTAD. It would be useful to clarify where UNIDO's remit ends and where e.g. the WHO's starts. Participation by representatives of other UN agencies could have been useful in this respect.

The use of "case studies" as a methodology was raised in connection with most of the five studies. This would provide a useful contrast to the theoretical approach (particularly for the techno-economic analysis), but for each study, the case-studies should be closely geared to the specific objectives of that study.

Several suggestions were made as to how UNIDO might be in a position to generate funds, thus alleviating (to a degree) the financial constraints to which it has to work. Suggestions included the sale of the second global study and the supply of a software programme to developing countries to assess the efficiency of a production process.

Collection of Data

The availability of good, reliable statistical data will have relevance for all the five studies. The problems of data collection are universal, not just exclusive to UNIDO, and UNIDO is in a good position to set up an extensive data base.

UNIDO should accept its limitations, i.e. it should not waste time chasing confidential data but, at least initially, concentrate on data which is readily accesible.

UNIDO should use its strengths to the greatest advantage. For example: it is in a position to approach governments for data; it does have access to UN statistics plus the data bases of other UN agencies; it can approach pharmaceutical companies for data, either directly or indirectly via the national PMAs or the IFPMA.

Pharmaceutical companies do have substantial data bases and if they have been unwilling to provide data in the past, I would suggest it is because UNIDO has been asking the wrong questions. It is unrealistic to expect companies to provide confidential data but there should be no difficulty in obtaining data regarding companies' activities in developing countries. Hoechst, for example, has made a point of publicising such data.

UNIDO is in a good position to build up an extensive data base for three main purposes:

(i) its own use;

(ii) to assist developing countries; and

(iii) for other external users.

(Again, this last point could represent another way of generating funds by providing an information service for which external users could pay).

Several participants expressed their willingness to provide UNIDO with data and these offers should be followed through. In Scrip's case, we might be willing to offer the following:

(i) Country reports we have prepared, for example on India;

(ii) Copies of the data contained in our country files;

(iii) Names of contacts, both in developing countries and in pharmaceutical companies who might be willing to assist UNIDO;

(iv) Copies of data on multinational companies' activities in developing countries.

N.B. UNIDO should try and obtain a copy of a report by Information Research Ltd on "The Opportunities for Pharmaceuticals in the Developing Countries to the Year 2000", since it contains much data on the developing countries, including projections. Scrip might also be able to assist here.

It was suggested that UNIDO might approach pharmaceutical companies to conduct studies/collect data on its behalf. If so, then it should be borne in mind that this might jeopardise credibility.

Each study should be clearly structured in terms of its objectives, scope and suggested methodology. The resources available in terms of time, finance and people should be taken into account. The terms used should be clearly defined and where more than one term is availabe to describe the same concept, one should be selected and adhered to throughout the studies.

UNIDO could do a lot to improve the presentation of its reports. Often the issues are clouded, sentences do not make sense, words are used out of context, etc. It is understood that UN reports on meetings where a consensus has been achieved must be very carefully worded to reflect the views of participants, but surely this does not also apply to background studies. It should not be necessary to have to read a study several times in order to grasp the issues at stake, particularly if studies are used for consultation meetings. What is important is to present the issues in a clear, lucid, readable manner and this could be much improved without losing credibility or running the risk of mis-representation or misinterpretation. It would be to UNIDO's advantage to develop a reputation for the production of high quality reports, particularly, for example, if it intends to sell the second global study as a way of generating funds.

E. Meneses
Consultant to the UNIDO Secretariat
8 December 1982

EVALUATION OF THE DISCUSSIONS

A. Recommendations

It was explained by the Secretariat that the Global Study would go through 3 different stages[1/]. In my opinion the following approach could be considered in this context. The preliminary draft should be circulated among various branches in the headquarters. This is the most crucial stage of the study and it must be tested by a forum of experts/consultants wherein developing countries and industrialized countries should be adequately represented. This testing phase of the study is important since it might avoid objections at the Consultation, thus contributing to the productivity of the latter. The final draft of the global study would be tested at the Consultation Forum and therefore no other specific action would be required at this stage. In respect of the revision of the final draft for amendments/additions agreed upon by the Consultation Forum, it is hereby proposed that said draft should be tested and analysed by a small group to which some participants to the Methodology/Consultation meetings could be invited.

The offer made by some participants as regards production/consumption data on the 26 essential drugs, country studies and the like must be traced. Appropriate follow-up must be established, letters shall be addressed to developing countries requesting data and support to the preparation of the global study.

Bearing in mind that the Sectoral Studies Branch plans to extend the methodology of this meeting to forthcoming studies on other sectors it is advisable that the programmed activities in the months to come be overcome in such a way that the experience that will be gained by implementing the outlined methodology could be utilized when similar studies in other industrial sectors are undertaken.

1/ See Annex III, overall time-schedule

The objectives of the study must provide developing countries with the elements required for the establishment of a pharmaceutical industry in said countries. Obviously these guidelines must follow the orientations of the Lima Declaration and they must adhere to the recommendations of the First Consultation Forum.

The stages through which developing countries are confronted when the implementation of a pharmaceutical industry is under consideration have been identified by UNIDO and grouped into five stages as indicated in the First Global Study. Developing countries must be clearly informed that the upper stage in pharmaceutical production that is production of active substances either by synthesis or by fermentation, or by extraction, should be the long term target in a number of countries but not a general principle applicable to all developing countries regardless. A number of local conditions must be taken into account before a decision on engagement in basic production is reached.

The pharmaceutical industry and the three subsectors grouped as per the proposed methodology must be examined in great detail in the body of the study. Considering that the study must contain a message addressed to the least developed countries, i.e. Black Africa, special emphasis must be placed on the subsectors of manufacture of Pharmaceutical Preparations (formulation activity) and on the subsector of Manufacturing of Biological Products in as much as these two activities of pharmaceutical production could be considered feasible, a priori, in a large number of small developing countries.

The three subsectors however must be illustrated in the study when their classification is undertaken. The objective of this classification must be oriented to explain also to developing countries how the selection of drugs either for basic production or for local formulation should be initiated. The pharmaceutical dosage forms of the 26 essential drugs ought to be disussed whereas the complexity of the methods and the standard echnology could be examined. The generics' production issue nevertheless must be taken up as a primary objective. The methodology for the production of bulk drugs by fermentation could be included.

When reviewing the special features and characteristics of the sector their importance as regards the world economy, also the regional economies must be analysed. At this point the need of establishing a functional system of cooperation at country level as well as on a regional basis must be stressed in the study.

The pharmaceutical industry as an integral component of development must be examined by focusing the existing local conditions in the least developed regions. It must be thought that although the study will present a fair picture of the industry as a whole in both developing countries and industrialized countries, in fact it must turn into a dynamic tool to orientate, to some extent, the least developing countries.

It is obvious that the study must examine all the integral constituents of technical and scientific nature as well as the socio-political involvements. The issues concerning the availability of resources whether human to build up technical cadres and appropriate manpower infrastructure, or natural resources linked to raw materials of local origin used in basic production, they must be thoroughly analysed. The interlinkage with other industries, i.e. chemical, production of container material, etc. must be examined.

The global overview of the sector, although it must illustrate the worldwide picture of the industry it must be focused nevertheless towards the main developing regions. The existing gap between developing countries and industrialized countries as regards production/consumption of the 26 essential drugs before and after the First Consultation Forum must be clearly explained. The reliability and accuracy of the sources and of the supporting data must be thoroughly verified. When the status of the industry in developing countries is examined, it must be mentioned that little or no R + D has been accomplished in the developing world. It could be stated that this absence of R + D constitutes one of the main constraints for the growth of the pharmaceutical industry.

It is important that all constraints faced by developing countries during the establishment of their pharmaceutical industries be clearly examined so that developing countries could easily identify the main obstacles that they will encounter. In addition to the constraints identified in the draft outline of the study, developing countries must be suggested to enforce protective national laws focused to stimulate the establishment of nationalowned production plants and to include among their priorities for national production not only antibiotic but also active substances obtained by organic synthesis.

Developing countries however must be clearly warned that in some instances their engagement in basic production could not be too promising at the beginning in the sense that production costs could be expected to be high at times due to the well established dependence on imported intermediates, solvents and the like. Consequently it might well occur that the selling prices of locally produced bulk drugs might not be competitive at least for some time. To a large extent developing countries must be informed that this circumstance would be part of the price they have to pay to participate in the backward integration of pharmaceutical manufacturing.

The technoeconomic analysis of the manufacture of pharmaceutical bulk substances produced by organic chemical synthesis is one of the most important constituents of the study. This chapter must be carefully enlarged and reviewed not only to illustrate it with several examples of bulk drugs produced in different developing countries as well as industrialized countries but also to provide consistent and unquestionable conversion factors. The chemical as well as the mathematical equations must be incontrovertible.

The study should make an appeal to industrialized countries to provide developing countries on technical know-how, R + D support and training of manpower. This message if adequately expressed, could provoke a firm commitment from industrialized countries.

The issues identified by the First Consultation Forum such as availability of bulk drugs (at fair prices) and of intermediates (some of the latter are "monopolized"), contractual agreements and technology transfer were not discussed in length at the methodology meeting. These issues are crucial and to a large extent they illustrate the main constraints which have contributed to retard the growth of the pharmaceutical industry in developing countries. Therefore, the discussions of these issues within the body of the study should constitute one of the main outputs of the global study.

The consistence of the projections of consumption and production for the years 1990 and 2000 will be dependent on the accuracy of the data that could be obtained. By exercising some pressure on the industry a reasonable amount of data on the 26 essential drugs could be obtained. Said data together with projections made by using other indicators, such as the GNP and the like could assist to build a rough estimation of the production/consumption trends during the last decade of the century.

The above stated required data will assist in the preliminary projections, nevertheless other elements must be taken into account in figuring out a viable scenario.

A favourable picture of a production scenario in developing countries will depend a great deal on topics such as strengthening co-operation from the most advanced developing countries in the pharmaceutical sector mainly in the areas of technological development and manpower training whereas financing requirements could be provided by international financing groups, i.e. World Bank and the like, so that production goals could be accelerated before the turn of the century beyond the current trends. This means that it would be unacceptable to consider that the present stagnation of the pharmaceutical industry will continue to exist.

The consumption trend in the years to come will continue to grow due to demographic factors, broader health budgets, etc. However, a negative element that will retard the increase of consumption of bulk drugs in developing countries can be identified as the well-known increase in poverty throughout the world within the context of the population growth. In other words the consumption of bulk drugs will not increase precisely parallel to the population growth as regards developing countries. It must also be reckoned what share of the demand will be covered by pharmaceutical producers within the developing regions and how much will be supplied by foreign sources. In drawing the scenarios it must be clearly illustrated how much will correspond to developing regions and what proportion will be shared by industrialized countries.

Considering the anticipated growth in preventive medicine the projection for production/consumption in the area of biologicals must foresee a substantial increase in developing contries above the current trends whereas it must only follow the demographic growth in industrialized countries.

Developing countries by the turn of the century will also increase their production/consumption of essential drugs in a substantial proportion as long as they learn to pool their capabilities and their resources within a system of regional co-operation.

B. Organization of the Meeting

The meeting was well planned and efficiently organized. All issues were discussed in depth and the participants provided constructive contributions on the various topics submitted for the appraisal of the floor. The forum was attended by delegations from developing and industrialized countries, thus providing a world-wide view of the problems inherent to the pharmaceutical sector. The deliberations nevertheless would have been more fruitful if the invited parties both from Black Africa and Arab Africa would have attended the discussions. Their views however will be reflected in the final report in as much as they have been requested to submit their written comments. Likewise it would have been convenient to invite participants from other developing regions such as Southeast Asia or the Caribbean. The delegation from planned economies nevertheless could have been more numerous.

The structure of the system of consultations was clearly described as well as its aims and targets. Perhaps it would have been advisable to emphasize the "dialogue concept" as a constructive means to reduce the distance between the needs of developing countries and the promises from industrialized countries. A detailed aide-mémoire which could have been provided to the participants would have familiarized them with the system thus allowing more time to concentrate on the specific issues of the meeting. Furthermore, it would have been advisable if other departments in the headquarters, such as the Transfer of Technology Branch or the Industrial Planning Section would have attended the meeting, providing thereby active participation during the discussion. The quality as well as the quantity of the documents distributed to assist the discussions was fair, although some participants did not receive some papers ahead of time.

The visual aid was in order and the projected slides were not only informative but clear and concise. The use of slides, blackboard, etc. by the participants is hereby suggested in forthcoming meetings.

Sector Study Methodology Meeting I

1-3 December 1982

List of Participants

Ms. Pamela Barnacal
SCRIP
18-20 Hill Rise
Richmond, Surrey
England

Ms. Margaret Cone
I F P M A
P.O. Box 328
CH-8035 Zuerich
Switzerland

Mr. George von Haunalter
SRI International
333 Ravenswood Ave.
Menlo Park, California
U.S.A.

Mr. Bengt Jönsson
Department of Health and Society
University of Linköping
Linköping
Sweden

Mr. V. Malik
Joint Secretary and Commissioner
of Drugs
Ministry of Petroleum, Chemicals
and Fertilizers
383 Shastri Bhavan
New Delhi, 110001
India

Mr. E. Meneses
Rua Barao de Jaguaribe, 326
Apt. 101
22421 Rio de Janeiro
Brazil

Mr. B. Mezey
Róbert Károly Krt. 24/IX/108
H-1138 Budapest
Hungary