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FACTORS HAVING A BEARING ON INDUSTRIAL DRUG POLICY*

Synopsis of studies

made by

United Nations Agencies

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CONTENTS

INTRODUCTION

(i) The Second Consultation on the Pharmaceutical Industry (Budapest, Hungary, 1983) which discussed the paper 'Need for Drug Policies'1/ recommended that in order to support the efforts of developing countries to formulate national industrial drug policies with particular reference to pharmaceutical production, the experience of developing and developed countries in the form of studies already produced by the United Nations agencies should be studied by UNIDO and relevant factors having a bearing on an industrial drug policy should be extracted and circulated to developing countries.2/

(ii) This study which has been prepared* in pursuance of this recommendation is based on the findings and recommendations contained in the various studies and reports/papers prepared by United Nations Industrial Development Organisation (UNIDO), United Nations Conference on Trade and Development, (UNCTAD), United Nations Centre for Transnational Corporations (UNCTC), World Health Organistion (WHO) and other relevant documents having a bearing on industrial drug policy. A selective list of the reports and studies made by UN agencies may be seen at Annex. I.

(iii) So far as an industrial drug policy is concerned, the studies discuss several elements of a drug policy such as preparation of a list of essential drugs; centralised bulk purchasing under generic names; establishment of local production facilities; development and transfer of technology, promotion of research and development; regulation of prices, quality control; regulation of foreign investment; training of personnel; safeguards against marketing harmful drugs; enactment of appropriate legislation; setting up of administratiave machinery to administer drug policy; regional and sub-regional cooperation etc.

iv. Briefly stated, the studies:

(a) describe the situation regarding health, pharmaceutical production and supplies in the developing countries.

(b) examine the various elements of the pharmaceutical policy and highlight the shortcomings/deficiencies in the implementation of the policy.

(c) **Identify both general and specific guidelines/policy measures required to formulate and strengthen the major elements of an industrial drug policy suited to the level of development and technological capabilities of the country concerned.**

(v) The studies made by various UN agencies have brought out into sharp focus the fact that since the developing countries vary greatly in their health situation, stages of development, technological capabilities, natural resources,

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1/ Need for drug policies - UNIDO-ID/WG/393/15.

2/ Second Consultation on the Pharmaceutical Industry - ID/WHO/393/19 p.9

* Contribution of Mr. S. Ramanathan, Secretary to the Government of India, Cabinet Secretariat, New Delhi, in preparation of this study is acknowledged.

etc., the objectives and elements of an industrial drug policy in each country would have to be tailored to meet the needs of each and in the light of the health scenario and stage of development of the pharmaceutical industry. For example, in countries with practically no manufacturing capability the elements of an industrial drug policy will be few, while in countries where indigenous industry is well developed and competes with foreign firms, the policy will be comprehensive, embracing many elements. As a country progresses from one stage of development to another, the policy would have to be reviewed and changes made keeping in view the objectives of the policy. However, the point is also emphasised that, irrespective of the stage of development, it is important for the developing countries to ensure that major elements of the policy, which are inter-dependent, are reflected by an appropriate combination of the elements in the industrial drug policy for a given country.

(vi) The guidelines suggested, and recommendations made by UN agencies in the various studies have had an important influence on the evolution of national policies having a bearing on health care and domestic pharmaceutical production in several countries. New policies, laws and regulations were adopted by them, combining, as appropriate to their specific national conditions, many elements of an industrial drug policy described in UN studies, such as preparation of a list of essential drugs, centralised bulk purchases, pricing of drugs, quality control, use of generic names, changes in industrial property laws, and progressive production of formulations and drugs.

Role of UNIDO

(vii) The studies also refer to the important role played by inter-national organisations such as, UNIDO, UNCTAD and WHO, in providing technical assistance and other advisory services to developing countries in the formulation and implementation of the various elements of a pharmaceutical policy. In this context, the role of UNIDO in promoting the pharmaceutical industry in developing countries by the programmes it has undertaken to support and strengthen some of the major elements of an industrial drug policy assumes significance. UNIDO's technical assistance programmes in the areas of transfer of technology for manufacture of bulk drugs/intermediates, pharmaceutical dosage forms and for design, construction and management of plants; supply of machinery and equipment; training of personnel; multipurpose plant for group of products; utilisation of medicinal plants; and the global consultations, workshop/seminars organised by it on topical policy issues having a bearing on the promotion of the pharmaceutical industry, have substantially contributed to the development of the technical expertise and technological capability in several developing countries for the establishment and operation of pharmaceutical pl nts.

Coverage of this Study

(viii) This study deals with the following factors/elements having a bearing on an industrial drug policy.

a. The health situation and production profile in developing countries which underline the urgency of improving pharmaceutical production facilities and health care systems in developing countries.

b. Formulation of an industrial drug policy for each developing country with clearly defined objectives and priorities.

c. Adoption of an essential drugs list for treating the most common diseases of the country and the preparation of an essential list of drugs for local production.

d. Centralised bulk purchases in generic names on the basis of competitive tenders.

e. Establishment of an indigenous pharmaceutical industry, the steps involved, the stages of manufacture and the technology and infrastructure required.

f. Importance of technology policy; the infrastructure required to acquire and absorb technology and the need to regulate technology agreements.

g. Research and development in developing indigenous technology and development of new drugs suited to the needs of developing countries.

h. Review of industrial property laws to safeguard the interests of the developing countries.

i. Regulation of role of TNC's in accord with national objectives and priorities.

j. Pricing of drugs with a view to keeping them as low as possible and the administrative machinery required to implement the pricing scheme.

k. Control over quality of drugs imported or locally manufactured and the legal framework and administrataive machinery required for ensuring quality.

l. Marketing of pharmaceuticals and the need for disseminating scientific information about drugs. Safeguards against marketing of unsafe drugs.

m. Training of technical personnel.

n. Legal framework and administrative machinery required for implementing drug policies.

o. Regional, sub-regional cooperation among developing countries.

p. Responsibilities of UNIDO, Government, the industry, the medical profession and consumers.

Chapter I

HEALTH SITUATION AND PRODUCTION PROFILE IN DEVELOPING COUNTRIES

Health Situation

There is a wide disparity between developing countries in health conditions and in their stage of development of the pharmaceutical industry.

2. The health situation in many developing countries is characterized by inadequate infrastructure and severe shortages of such basic requisites as adequate sanitation, safe drinking water, appropriate nutrition and health delivery systems. As a result, infectious and parasitic diseases take on epidemic proportions.

3. For the developing countries as a group, life expectancy at birth is about 53 years, as against 70 years for the developed regions. The low life expectancy at birth, which varies from 47 years in Africa to 61 in Latin America, can largely be attributed to very high death rates among children during the first year of life.1/ For those in developing countries, who reach the age of five, expectancy is only six to eight years less than in developed countries. However, these people suffer frequently from non-fatal diseases, which disrupts economic activities, often at critical times.

4. The most widespread diseases in developing countries are the water borne diseases, (intestinal, parasitic and infectious diarrheal diseases, typhoid, cholera) and airborne diseases (tuberculosis, influenza, pneumonia, diphtheria, meningitis etc.). These combined with malnutrition, account for the majority of deaths among the poores people in developing countries.

Health Care and Delivery Systems

5. It has been estimated that about 50% to 80% of the population in developing countries have no regular access to pharmaceuticals or to a health care delivery system. Drugs are not available on a regular basis in remote areas and villages which are often inaccessible.2/ Drug distribution is the weakest link in the health care delivery system.

6. Even though in recent years, national health policies have shifted sharply from expansion of facilities from hospital based care, towards expansion of rudimentary health services to the rural populations, the public financed health care systems do not provide adequate access to essential service, except densely populated areas.3/

1/ Health sector policy paper - World Bank, 1980 p.10

2/ Guidelines on technology issues in the pharmaceutical sector in the developing countries. UNCTAD/TT/49 - p.16.

3/ Health sector policy paper - World Bank 1980. p.18

Public Distribution System

7. It is necessary, therefore, to devise a system of distribution that will reach a majority of people in the rural areas. However, since the public health budgets of most of the developing countries may not be able to bear the heavy expenditure on the engagement of an increasing number of physicians, they cannot adopt the system followed for distribution in developed countries. An alternative system that is emerging as a result of the experience gained in many developing countries, is a multi-tier system, involving general physicians and specialists at the referral and central hospitals. At the remotest delivery point there would be a voluntary community health worker who has some education, may be selected by the community, and is adequately trained in first aid, symptomatic diagnosis of simple illnesses and drug administration. At the same time, there would be the health workers and the health assistants (para-medical personnel) who have received more elaborate training and can act as a link between the community worker and the para-medical health centre which covers a number of villages staffed by general physician.4/

Profile of Pharmaceutical Production and Consumption

8. The pharmaceutical industry exerts a profound influence over the effectiveness of policies to protect health and promote economic and social development. It has, at the same time, a direct influence on the establishment of other industries, on international trade and on the transfer and development of technology.

9. The current scenario of the world pharmaceutical industry reflects a lopsided development, which is unsastisfactory from the point of view of the developing countries. While two-thirds of the world population live in the developing countries, they consume barely 14% of the world production of pharmaceuticals, even though their need for drugs is much greater than that of the people in the developed countries, which account of 86.27% of the world consumption.

10. Pharmaceutical production pattern is even more lopsided. It is concentrated in the developed countries which account for 90% of the world production. The share of the developing countries is only 10%, of which nearly two-thirds come from a relatively few countries - Argentina, Brazil, Egypt, India, Mexico and South Korea.5/ Only a few developing countries possess an established pharmaceutical industry with backward integration for bulk drug production.6/

11. To satisfy their pharmaceutical requirements, developing countries, therefore, depend heavily on imports from developed countries. In 1980, developed countries accounted for 95% of total world exports and 68% of imports. The share of the developing countries was 5% of world exports and 32% of world imports. Since most developing countries lack the basic chemical processing industry, they import mainly finished or semi-finished products, rather than basic or intermediate products, requiring extensive local processing.

4/ Guidelines on technology issues in the pharmaceutical sector in the developing countries UNCTAD/TT/49. p.16

5/ Technology policies and planning for the pharmaceutical sector in the developing countries TD/B/C. 6/56. p.IX

6/ Ibid. p. IX.

Chapter II

INDUSTRIAL DRUG POLICY AND ITS OBJECTIVES

12. Providing adequate health care for the people of the developing countries presents a significant and complex challenge. Despite the efforts of Governments, international organisations and voluntary agencies, pharmaceuticals are available occasionally, or not at all, to 70% of the citizens of many developing countries. This is because of the non-existent or inadequate pharmaceutical manufacturing capability, and the poorly functioning or non-existent health care infrastructure, in many developing countries. The case studies on the health and pharmaceutical situation in developing countries have spotlighted the great need for drugs in the countries in the context of the inadequate preventive public health measures. Drugs should therefore, provide the main prophylactic and curative support against ill-health and diseases.

Integrated Policy for the Pharmaceutical Sector

13. The studies conducted by U.N. agencies have highlighted the need for formulating an integrated policy/plan for the development of the pharmaceutical industry which will deal not only with procurement and production but also with several other interrelated matters, including distribution and a health services delivery programme, in order to ensure supply of appropriate drugs to the whole population. Keeping this broad objective in view, special attention has to be paid to the industrial aspects of a drug policy which are concerned with the establishment of local production facilities and the policy measures/instruments required for promoting and developing the drug industry.1/

Objective of an Industrial Drug Policy

14. The principal aims of industrial drug policy are to promote the local pharmaceutical industry and develop a self reliant technology base. To achieve these aims it is essential that Governments should spell out clearly the objectives and elements of the policy, enact the legislation for regulating various aspects of the policy and establish the administrative organisations for implementing the policy.

Objectives of Industrial Drug Policy in a Developing Country

15. It may be useful at this stage to briefly outline the broad objectives of the industrial drug policy of a developing country by referring to the concrete example of India, where the New Drug Policy, which was announced in 1978 states them as:2/

i) to develop self-reliance in drug technology;
ii) to provide a leadership role to the public sector;
iii) to aim at quick self-sufficiency in the output of drugs with a view to reducing the quantum of imports;
iv) to foster and encourage the growth of the Indian sector;

1/ UNIDO experience in implementing pharmaceutical projects in developing countries - UNIDO/IO.570. p.1

2/ Statement of India's New Drug Policy - 1978

v) to ensure that the drugs are available in abundance in the country to meet the health needs of the people;

vi) to keep a careful watch on the quality of production and prevent adulteration and malpractices;

vii) to offer special incentives to firms which are engaged in research and development; and

viii) to provide other parameters to control, regulate and rejuvenate this industry as a whole, with particular reference to containing and channelising the activity of foreign companies in accord with national objectives and priorities.

14 Point Programme of Non-Aligned Nations

16. Since cooperation in the pharmaceutical sector among developing countries has engaged the attention of the Non-Aligned Countries, it may be useful to refer to the 14 points mentioned in Resolution No. 8 on 'Economic Cooperation among Developing Countries' in the field of pharmaceuticals adopted by the Sixth Conference of Heads of States or Governments or Non-Aligned countries held in Havana, Cuba, (1979). These points take care of practically all the elements of an industrial drug policy. These are:-

i) elaboration of drug lists and formularies;

ii) pooled procurement, inventory control and forecasting systems at the regional level;

iii) elaboration of legal principles relating to industrial property;

iv) elaboration of tenders and master contracts for drug imports;

v) provision of information on sources of supply and technology;

vi) assisting in the screening and evaluation of drug imports;

vii) price monitoring, control of transfer pricing and technology import mechanisms;

viii) promoting industrial cooperation among member countries;

ix) assisting in securing equipment imports on the most economic terms

x) organising training of government officials in health policy, procurement, production, etc;

xi) the production of pharmaceuticals and intermediates for several countries;

xii) research in laboratory, pilot plant, semi-industrial and industrial processes for the introduction of new products and the adaptation of imported technologies;

xiii) the preparation of feasibility reports on pharmaceutical development projects;

xiv) ensuring quality control in respect of raw materials, intermediates and finished goods.3/

3/ Report and recommendations of the workshop on trade and technology in the pharmaceutical sector-UNCTAD/TT/48 - Annex I p.1/2

Recommendations made by UN Agencies and International/Regional Conferences

17. Similar recommendations for formulation of an industrial drug policy, with emphasis on the various elements of a drug policy, outlined above, were made by a Joint Mission to the Caribbean Region organised by the UN Action Progamme for Economic Cooperation, (Georgetown, Guyana (1977)4/, the Third International Conference on Transfer and Development of Technology in Developing countries, under More Favourable Conditions in the Pharmaceutical Industry, (Belgrade, Yugoslavia, 1979)5/; Report of the Inter-Agency Task Force on Pharmaceuticals under UNDP Project, executed by the Government of Technical Cooperation for development, UNCTAD and WHO, (1979)6/; the UNCTAD Workshop on the Trade and Technology Policies in the Pharmaceutical Sector in the Caribbean Region (1980)7/; and the UNCTAD Workshop on Trade and Technology Policies in the Pharmaceutical Sector in the African Region8/;

18. UNIDO has also highlighted the importance of the major elements of an industrial drug policy as necessary pre-conditions for the establishment of a pharmaceutical industry.9/

19. To sum up, based on the evaluation of the experience of developing countries, the recommendations in various studies conducted by UN agencies and in international/regional conferences, each developing country may, formulate an industrial drug policy, embracing a few or all the following elements, depending upon the health situation, stage of development of the pharmaceutical industry and the scientific infrastructure available in the country:

1. prepare a list of essential drugs, keeping in view, health requirements and a list of drugs based on it for local production.
2. institutionalise arrangements for making centralised bulk purchases on generic names based on competitive tenders.
3. establish its own pharmaceutical industry, in the private and public sectors, beginning with formulation and packaging of bulk drugs and intermediates in stages and render all encouragement and assistance.
4. prepare a technology plan for acquisition and absorption of foreign technology, and for development of indigenous technology.
5. promote research and development in technology, upgradation of processes and development of indigenous systems of medicine.
6. enact legislation for quality control of drugs.

4/ Guidelines on technology issues in the pharmaceutical sector in the developing countries - UNCTAD/77/49 - Annex II, p.42

5/ Ibid - Annex IV - p.48

6/ ibid - Annex V - p.50

7/ Ibid - Annex VII - p.53

8/ Ibid - Annex XII - p.65

9/ Note on UNIDO activities relating to pharmaceutical products in the context of primary health programmes - UNIDO/IOD.207 - p.2/3

7. initiate measures for regulating marketing and promotional practices and dissemination of drug information.

8. enact legislation providing safeguards against marketing of unsafe drugs.

9. set up a system of price monitoring or price control, formally or informally.

10. to enact legislation to regulate investments and production by transnational corporations in pharmaceutical industry.

11. to set up the necessary legal framework and administrative machinery to administer the drug policy.

12. cooperate with other countries in the region or sub-region, on various components of the drug policy, in respect of which, there will be scope for benefiting by collective action.

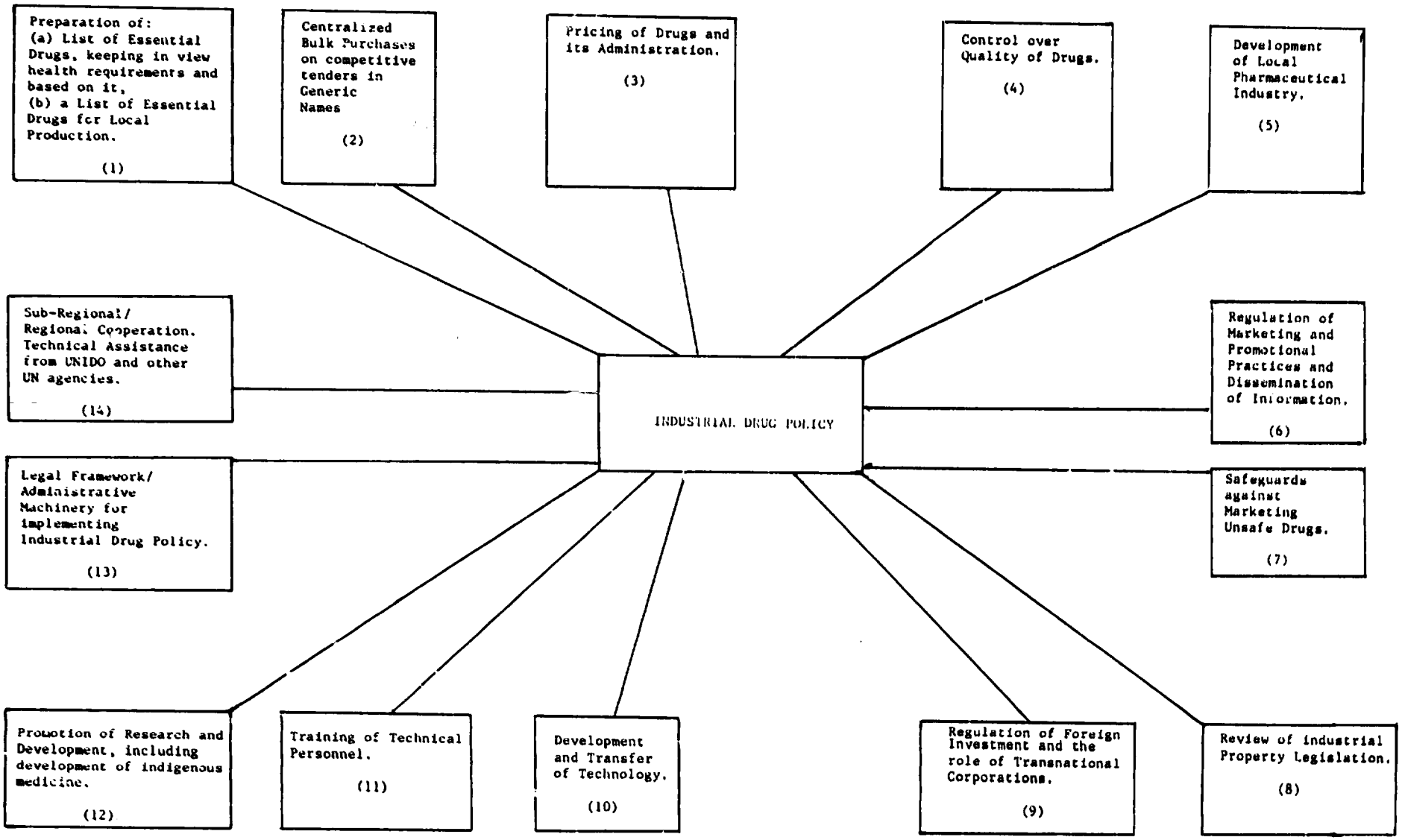
Need to Include Major Elements in the Policy

20. It would be seen from the foregoing that an industrial drug policy embraces many elements, which would necessarily vary from one developing country to another, depending upon the stage of development, technological capability, natural resources etc. Obviously in countries with practically no local manufacturing capability, the elements of the policy will be few, while in countries where the indigenous drug industry is well developed and competes with foreign companies, the policy will be comprehensive, embracing several elements. As a country progresses from one stage of development to another, the drug policy would have to be reviewed and changes made in it, keeping in view the objectives of the country. However, irrespective of the stage of development, it is important to ensure that major elements of the policy which are inter-dependent are reflected by an appropriate combination of the elements in the industrial drug policy for a given country.

21. There is plenty of experience, expertise and documentation available in the formulation and implementation of industrial drug policies in some of the developing countries themselves and in international agencies such as UNIDO, WHO, UNCTAD, etc. It is for the developing countries to reach out to this fund of knowledge and experience and benefit by them.

22. The various elements of an industrial drug policy have been shown schematically on page 7.

INDUSTRIAL DRUGS POLICY AND ITS ELEMENTS



Chapter III

ESSENTIAL DRUGS

Preparation of a List of Essential Drugs

23. It is now well recognised that the first step towards a rational drug policy is the preparation of a list of essential drugs for treating the large majority of diseases in a country.1/ In the light of experience gained both in the developed and developing countries, it is now generally accepted, as confirmed by the WHO Expert Committee, that the number of drugs necessary for treating the most common and widespread diseases is relatively small.

WHO's List of Essential Drugs

24. The lead in assisting the developing countries in identifying and suggesting a list of essential drugs was taken by the WHO by appointing an Expert Committee on Essential Drugs which recommended in 1977 a model list of essential drugs. This list was subsequently revised and updated in three further reports, the last being in 1985. The model list consists of bulk drugs and selected formulations thereof falling in 27 therapeutic groups.2/ A separate list of 23 drugs appropriate for use in primary health care was also recommended. Most of the developing countries have limited resources for procurement, raw material production, quality control arrangements, storage, distribution and finance; and what is important is to use them in as effective a manner as possible to provide for the needs of the population.3/ Since there are great differences between countries, the preparation of a drug list of uniform general applicabililty and acceptability is not feasible or possible. Therefore, the list of essential drugs suggested by the WHO is a model which can form a basis for countries to identify their own priorities and to make their own selection.4/

UNCTAD Studies

25. The adoption of an essential list is one of the preconditions for a fruitful pharmaceutical industry in the developing world.5/ The UNCTAD in their studies on selected countries, and in the document, dealing with major issues

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1/ Report and recommendation of the workshop on trade and technology policies in the pharmaceutical sector in the Caribbean Region-UNCTAD/TT/41/Rev.1 p.4

2/ Technical Report Series-722-WHO 1985. p.14 to 27.

3/ Ibid - p.6

4/ Ibid - p.6

5/ Global Study of the pharmaceutical industry - ID/WG.331.6 p.89

in the transfer of technology in the pharmaceutical sector have emphasised, both the importance and the urgency of preparing a list of essential drugs, not only in the countries concerned, but also in the region or sub-region.6/ to 12/

26. The Fifth and Sixth Summit of Heads of State or Governments of Non-Aligned Countries (1979) recommended the preparation of a list of pharmaceutical needs of each developing country and the formulation of a basic model list of such needs as a general guideline for action by the developing countries.13/

List of Essential Drugs in Developed Countries

27. It may be mentioned that it is not the developing countries alone which have to carefully prepare a list of essential drugs. In developed countries also there is a growing concern about controlling the drug use and the expenditure on, and the prices of drugs and measures have been taken, e.g. in Norway, Sweden, and Australia to successfully reduce the large number of preparations in the market by adopting a list of essential drugs.14/

6/ Report and recommendations of the workshop on trade and technology policies in the pharmaceutical sector (Abidjan, Ivory Coast) - UNCTAD/TT/48 p.9

7/ Guidelines on technology issues in the pharmaceutical sector in developing countries - UNCTAD/TT/49. p.12

8/ Technology policies in the pnarmaceutical Sector in developing countries - UNCTAD/TT/7 p.6

9/ Major issues in transfer of technology to developing countries - TD/B/C.6/4. p.51

10/ Technology policies in the pharmaceutical sector in Venezuela - UNCTAD/TT/25. p. 9/10

11/ Technology policies in the pharmaceutical sector in the Phillipines UNCTAD/TT/36 p.26

12/ Major issues in transfer of technology to developing countries - A case study of the pharmaceutical industry - TD/B/C. 6/4 p.51

13/ Guidelines on technology issues in the pharmaceutical sector in the developing countries - UNCTAD/TT/49 Annexes I and vi p.41 and 52

14/ Report and recommendations of the workshop on trade and technology policies in the pharmaceutical sector - UNCTAD/TT/48 p.7

Criteria for Selection of Essential Drugs

28. According to the WHO, essential drugs are those that satisfy the health needs of the majority of the population; they should, therefore, be available at all times in adequate amounts and in the appropriate dosage forms. The choice of such drugs depends on many factors such as pattern of prevalent diseases; the treatment facilities; the training and experience of available personnel; the financial resources; and the generic, demographic and environmental factors.15/

29. As a measure of caution, WHO Committee has recommended that only those drugs should be selected for which sound and adequate data on efficacy and safety are available from adequate clinical studies and for which evidence of performance in general use in a variety of medical settings has been obtained.

30. Since the first report of the WHO Committee on Essential Drugs was published in 1977, the concept of essential drugs has become widely recognised as useful. More than 80 countries have now prepared according to WHO, a list of essential drugs according to the needs and the relative programmes are, in some cases, in an advanced stage of implementation.16/ Additionally, various non-Governmental organisations and UN agencies have also adopted their own list based on the WHO list.

31. As stated by WHO, the experience so far with the Essential Drugs List (EDL) has been more than gratifying; the advantages are scientific, educational and economic. On the scientific and educational side, an EDL leads to a more rational and prominent use of drugs and facilitates the production of a National Drug Formulary. On the economic side, an EDL reduces expenditure on medicines, avoids drug misuse, encourages local production and increases the proportion of health care budget that can be devoted to other items.17/

National Formulary

32. In order to lay standards for the drugs manufactured locally as well as those imported, a National Formulary should be compiled which should reflect preference for the identified essential drugs.18/

15/ WHO - Technical Report Series No. 722 p.8

16/ Ibid - p.7

17/ World Health - WHO. December 1985

18/ Conclusions and recommendations adopted at the third international conference on transfer and development of technology in the developing countries under more favourble conditions in the pharmaceutical industry - Belgrade (1979) - UNCTAD/TT/49, Annex-IV p.48.

Local Committee

33. Each country should appoint a Local Committee comprising not only specialists in clinical medicine and pharmacology but also general practitioners and other health workers. The advice of pharmacists is especially valuable on dosage forms, packaging and distribution problems. The national drug list should be reviewed every two or three years and new drugs should be introduced only if they offer a distinct advantage and are reasonably priced.19/

34. Essential drugs must be accompanied by adequate information required for their safe and effective use. Model information sheets on all drugs included in the WHO model list are being prepared by WHO according to a standard format. These can be easily translated into any language and can be used to assemble a local formulary. The use of these information sheets will, therefore, make it unnecessary to rely on whatever information material may be provided by manufacturers.20/

UNIDO List of Essential Drugs for Integrated Production

35. As part of their responsibility for the establishment of national or regional pharmaceutical production facilities, and the transfer of technologies to developing countries, UNIDO has, in consultation with WHO, developed an illustrative list of 26 essential bulk drugs for integrated production from intermediates or basic raw materials, for treating the most common diseases prevalent in developing countries.21/ Out of these 26 drugs, UNIDO has identified 9 essential drugs, for which facilities for the local manufacture of active ingredients should be established in developing countries on a priority basis. These two lists may be seen at Annex II and III respectively.

19/ Guidelines on technology issues in the pharmaceutical sector in the developing countries UNCTAD/TT/49. p.12

20/ Ibid - p.12

21/ Illustrative list of drugs prepared by UNIDO in consultation with WHO (1980)-ID/WG.331/8

Chapter IV

CENTRALISED BULK PURCHASES

36. The procurement of finished bulk drugs, raw materials and chemical intermediates of the appropriate quality at as economic a price as possible is an essential component of any plan for optimum utilisation of resources and, in the case of imported drugs, optimising the use of foreign exchange resources. The aim of a centralised procurement in developing countries is to guarantee an uninterrupted supply of high quality bulk drugs at the lowest world market prices.1/ A centralised procurement system has several obvious advantages in developing countries, whatever their level of development, in terms of organised market intelligence; advantages of bulk buying and therefore greater bargaining power; management of quality control of imported products; easier control of trade practices which are dangerous to health; ensuring that domestic drug manufacturers, including subsidiaries of foreign companies, purchase their raw materials at equitable prices; enabling the national pharmaceutical system to be built around essential drugs.2/ The ultimate objective through such procurement is to assist local manufacture at reasonable cost.

37. The studies made by the UN agencies have noted the beneficial purchases made worldwide in several countries, through centralised bulk purchases and made recommendations for establishing a central pool agency for purchases through open tenders.3/ to 12/

1/ Global study of the pharmaceutical industry - ID/WG.331.6 p.91

2/ Guidelines on technology issues in the pharmaceutical sector in the developing countries - UNCTAD/TT/49 p.15

3/ A technology policy in the pharmaceutical sector in the United Republic of Tanzania - UNCTAD/TT/35 p.viii

4/ Technological policies in the pharmaceutical sector in Venezuela UNCTAD/TT/25 p.23

5/ Technology and development perspectives of the pharmaceutical sector in Ethiopia - UNCTAD/TT/58 p.31

6/ Technology policies in the pharmaceutical sector in Cuba - UNCTAD/TT/33 p.19

7/ Technology policies in the pharmaceutical sector in Nepal - UNCTAD/TT/34 p.29

8/ Report and recommendations of the workshop on trade and technology policies in the pharmaceutical sector (Abidjan, Ivory Coast) - UNCTAD/TT/48 p.18

9/ Report and recommendations of the workshop on trade and technology policies in the pharmaceutical sector in the Caribbean Region - UNCTAD/TT/41 Rev.1/p.11

10/ Case studies in transfer of technology: Pharmaceutical policies in Sri Lanka TD/B/C.6/21 p.3

11/ Technology policies and planning for the pharmaceutical sector in the developing countries - TD/B/C.6/56 p.4

12/ Technology policies in the pharmaceutical sector in the Phillipines - UNCTAD/TT/36 p.26

38. A joint mission organised by UNCTAD, CARICOM and the Trade, Transport and Industry sector of the United Nations Action Programme for Economic Cooperation, in their report in 1977, recommended the establishment of a Central purchasing agency for procurement of pharmaceuticals, and added that, in certain cases, it may be appropriate to establish this agency in the first instance, for the procurement of the public sector requirements and thereafter to extend it to include the private sector.13/

Advantages of Centralised Pooled Purchases

39. Countries that have adopted a system of centralised and pooled purchases in the place of fragmented procurement systems which exist in many developing countries, have been able to effect economies,diversify sources of supply and regulate distribution of the bulk drugs and raw materials at uniform prices. The centralised purchase of drugs limited to a national list of drugs, in addition to rationalizing purchases, would also help to rationalize purchasing procedures, storage, distribution, prescription, quality control and dissemination of objective drug information to health workers. Experience of some of the developing countries has shown that centralized purchase and distribution has several merits. Sri Lanka was able to save more than 50% of its expenditure on import of drugs.14/ In India, most of the principal bulk drugs are imported by the State Trading Corporation, an independent corporation; this has helped to regulate and equitably distribute at uniform prices major imported bulk drugs and also reduced the scope for transfer pricing. In Costa Rica owing to the centralized purchase of drugs through CCSS (Caja Costaricense del Seguro Social) there was a saving of about $6 million on the orders placed in 1978. This represented 40% of the total value of 1978 orders.15/

Experience of Developed Countries

40. It is not the developing countries alone that have in the recent years benefited by pooling the drug requirements and arranging procurement through a centralised designated agency. Some of the developed countries also have benefited. The experience of the American Food and Drug Administration has shown that bulk buying under generic name have achieved considerable savings in drugs purchased and dispensed under the Medicare and Medicaid programmes. In Sweden, centralised procurement through the National Corporation of the Pharmacists coupled with a single channel distribution had significantly contributed in reducing the cost of quality drugs to the consumer. The experience of PARCOST(Prescription at Reasonable Cost, Ontario, Canada) has shown that

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13/ "Towards a Regional Pharmaceutical Policy". Report of a Joint Mission to the Caribbean Region, organised by UNCTAD, CARICOM and the Trade, Transport and Industry sector of the United Nations Action Programme - UNCTAD/TT/49 Annexe II, p.42

14/ Case studies in the transfer of technology: pharmaceutical policies in Sri Lanka, TD/B/C. 6/21 Annex. p-1.

15/ Technology Policies in the pharmaceutical sector in Costa Rica - UNCTAD/TT/37. p.21

the introduction of a comparative drugs index indicating production cost and prices of drugs as well as their basic specifications, could assist in ensuring stable prices in quality drugs.16/

Agency for Procurement

41. A centralised procurement agency should preferably be a separate public corporation, not necessarily a Government department.17/ It should be run on commercial lines, managed by staff trained in business and management practices relating to trade, storage and inventory control. Initially, such an agency may act merely as a clearing house, but as the work develops, it may have to establish its own warehousing facilities. The agency may be assisted by an independent committee to advise on the quality aspects of the products. The prerequisites for centralised purchasing are a restricted list of drugs and the exclusive use of generic names. It will then be necessary to work out estimates of the quantities required annually or bi-annually. A minimum saving of 30% but sometimes as much as 50% could be made by centralised purchase.18/

42. A centralised purchasing system may be established in every developing country, whatever its level of development. In nearly all developing countries health care is delivered by both the public and private sectors. Centralised procurement may, therefore, initially have to be for public sector requirement only. After a period of time, when the system functions well, it could extend its operations to cover private sector requirements as well. To maximise its bargaining power, the purchasing agency should build up a market intelligence unit.

Regional Pooling

43. The total drug requirements of a number of small developing countries are too small for them to take advantage of economies of scale merely by centralising the procurement system. A way of resolving the problem would be for such countries in the same region to pool their drug purchases. through a regional centre. The first of such regional centres is to be established by the countries of the Caribbean region.19/

16/ Report and recommendations of the workshop on trade and technology policies in the pharmaceutical sector in the Caribbean Region - UNCTAD/TT/41/Rev.1 p.7

17/ Technology policies and planning for the pharmaceutical sector in developing countries - TD/B/C. 6/56 p.5

18/ Guidelines on technology issues in the pharmaceutical sector in the developing countries - UNCTAD/TT/49. p.15

19/ Ibid. p.15

The prerequisites of a regional pooled purchase programme are:

a. the drawing-up from national lists, of a common list of generic pharmaceutical substances which would meet the health needs of countries;

b. the drawing-up, on the basis of trade information (the volume and price of individual transactions), of a restricted list of products to be subject of pooled purchases.

c. the making of pooled purchases on the basis of international invitations to tender and with, so far as possible, the according of priority to suppliers;

d. the gradual assumption by the institutions already in existence or to be created of responsibility for quality control in relation to the entire range of drugs subject to pooled purchasing;

e. study and determination by each group of countries when setting up its pooled purchasing programme of the status and powers to be conferred on the regional procurement agency and the means of financing both the necessary investments (e.g. warehouse, stocks) and current operations (e.g. the collection of credits/debits).

44. There is a need for United Nations agencies to pool their efforts in assisting developing countries in:

a. Establishing an information system on drug prices and pricing system, drug management, drug evaluation, price of raw materials, packaging, etc.

b. Establishing collective procurement centres on a regional basis.

c. Disseminating information on the procurement system of international agencies (e.g. UNICEF) so that developing countries may benefit from the experience of these agencies.

d. Establishing and strengthening national procurement agencies.20/

20/ Guidelines on technology issues in the pharmaceutical sector in the developing countries. UNCTAD/TT/49. p.15

Chapter V

ESTABLISHMENT OF PHARMACEUTICAL PRODUCTION IN DEVELOPING COUNTRIES

45. An important element of industrial drug policy in a developing country is the development of the pharmaceutical industry. While the scope for development of the industry may vary from country to country, there is a growing awareness among developing countries that self reliance, both nationally and collectively in pharmaceuticals to the extent possible is a desirable goal which can be achieved in stages, provided the Governments of the countries have the political will and are committed to exploring all avenues of cooperation among themselves for inducting technology, arranging for pooling purchases of pharmaceuticals and organising marketing facilities.1/,2/ In fact, based on UNIDO's experience in developing countries, the crucial aspect is the Government's political decision to promote the development of a pharmaceutical industry.3/

Objectives in Promoting Pharmaceutical Industries

46. The major objectives in promoting pharmaceutical industries in developing countries are:-

a. To provide, in adequate quantities, products, essential to health care at prices within reach of most of population;

b. To set up relatively independent drug industries that will allow developing countries more freedom to form health care policies relevant to their particular needs at minimal cost, using locally available raw materials and production facilities, and also utilizing the existing traditional forms of medicine;

c. To contribute to the national economies of the developing countries.

d. By taking steps appropriate to the stage of development of the industry in these countries, i.e., formulation of drugs in dosage forms, operation of multipurpose plants, production of bulk drugs of plant and animal origin or production of drugs from intermediates to establish a self-sustaining industry.

e. To have a catalytic effect on industrial development in general. The pharmaceutical industry usually spearheads the development of chemical and chemical-based industries, as well as the ancillary products and engineering industries required to supply their needs;

1/ Report and recommendations of the workshop on trade and technology policies in the pharmaceutical sector - UNCTAD/TT/48 p.7

2/ Report and recommendations of the workshop on trade and technology policies in the pharmaceutical sector in the Caribbean Region - UNCTAD/TT/41-Rev.1 p.9

3/ UNIDO's experience in implementing projects in developing countries - UNIDO/IO. 570 p.5

f. To provide educational opportunities for young men and women in new disciplines of science and to provide employment for trained people.4/

Measures Required to Achieve the Objectives

47. The following are the principal measures to be taken to achieve the objectives:-

a. Establishment of a national list of essential drugs as a basis for rational development of the pharmaceutical industry in relation to the health needs of the population;

b. Improvement and strengthening of the scientific base for development and production of the traditional medicine and household remedies;

c. Development of repacking and formulation plants;

d. Development of manufacturing plants for sanitation products, in particular water-treatment agents, pesticides and disinfectants;

e. Formation of an infrastructural framework to advance the development and production of bulk drugs, including immunologicals and antibiotics, as well as their related basic materials such as intermediates, biologicals, plant products, chemical precursors, and various nutrient media;

f. Study and establishment of standards for tropical conditions, chemical engineering plant facilities and layout structures. Dosage forms also should be designed to withstand the high temperature and humidity conditions in tropical countries;

g. Development of manufacturing plants for dosage packaging (for example, pharmaceutical glass) and various other types of packaging materials;

h. Establishment of a comprehensive quality assurance system, including system of registration of drugs, specifications of standards and procedures, training of specialised personnel, in-plant quality assurance systems, etc.

i. Establishment of regulations relating to domestic and foreign corporate ventures and the importation of foreign drugs, intermediates and know-how;

j. Establishment of model manufacturing units in less developed countries and in the rural areas of more advanced developing countries. These units will formulate selected indigenous drugs, household remedies, antiseptics, infusions and other simple formulations, depending on the common ailments prevalent in the area;

4/ Appropriate industrial technology for drugs and pharmaceuticals - UNIDO - ID/232/10 p.4

k. Establishment of multipurpose plants to produce drugs from intermediates for a group of model manufacturing units;

l. Establishment of units for the extraction of active ingredients of plant products that can be cultivated in developing countries instead of the present practice of exporting them as crude drugs. This will improve the value added of the products exported to developed countries and give the developing countries the necessary foreign exchange reserves to import intermediates and other substances required for the manufacture of drugs to combat diseases common in the area.5/

Criteria for Selecting Drugs for Local Production

48. The criteria for selecting drugs for local production may include the following:-6/

a. The drug is widely used and required by the health authorities to treat prevalent diseases;

b. Its efficacy and safety in the treatment of diseases has been demonstrated and the WHO has endorsed its use;

c. The cost per treatment is low enough for the population to afford;

d. There are other special advantages of local manufacture as opposed to imports (lower costs of transport, availability of raw materials, saving of foreign exchange etc.);

e. A feasibility study of the project indicates that economic production could be ultimately attained taking into account the regional and interregional markets;

f. The manufacturing process is appropriate to conditions prevailing in the country;

g. The know-how for manufacture is available for use whether patented or not.

Illustrative List of Essential Bulk Drugs Identified by UNIDO for Integrated Production

49. As a part of its responsibility of assisting the developing countries, to establish national production facilities, the UNIDO has identified, in consultation with WHO, an illustrative list of 26 essential drugs (of these, 9 are for

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5/ Appropriate industrial technology for drugs and pharmaceuticals - ID/232/10 p.6

6/ Note on UNIDO activities relating to pharmaceutical products in the context of primary health programmes - UNIDO/WD/207 p.3

production on priority basis), for integrated production from intermediates or basic raw materials.7/ These drugs are required for treating the most common, widely prevalent and endemic diseases in developing countries. A large part of the technological knowledge required for the manufacture of the drugs is now in the public domain8/ as most of them are free of patents.9/ In fact, most of these drugs are manufactured in several developing countries and the relative technologies are available. These could be made available to the less developed countries on reasonable and equitable terms.

Stages of Development of Industry in Developing Countries

50. The pharmaceutical industry in developing countries is characterised by widely differing stages of manufacturing capability. While some of the least developed countries depend totally on imports of finished drugs and lack the most elementary formulation or packaging industry, the most advanced developing countries are able to manufacture active ingredients, process raw materials and even engage in the development of new drugs. In between, most other countries have reached intermediate stages of manufacturing capability which may involve the production of some intermediates from locally produced chemicals as well as the formulation and packaging of imported bulk drugs. For example, India, Argentina, Brazil, Egypt, Mexico and Republic of Korea have advanced production capability, mainly formulation and packaging; Costa Rica, Malaysia and Sierra Leone have little or no manufacturing capability. In countries with advanced manufacturing capability, the domestic sector meets most local needs of finished products, ranging from 83% of local consumption in Egypt, 97% in Mexico and almost 100% in India. In addition, both foreign and domestic firms are substantially integrated and capable of manufacturing, number of active ingredients from intermediate and raw materials. Such an advanced production capability is made possible by the existence of sophisticated chemical industry and a large bulk of technical personnel. Public sector also plays a predominant role in Egypt followed by some share of the market by public enterprises in Brazil, India and Mexico.10/

Phases in the Production Sequence

51. The setting up of a pharmaceutical industry, considered in reverse order to the production sequence, generally takes place in several distinct steps, starting with packaging and repackaging of bulk supplies and followed by dosage formulation. Then comes production of the raw materials (bulk drugs or active ingredients) from chemical products and medicinal plants. Consideration should

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7/ Illustrative list of drugs prepared by UNIDO in consultation with WHO - 1980 - ID/WG.331/8

8/ Guidelines for technology issues in the pharmaceutical sector in the developing countries - UNCTAD/TT/49. p.19

9/ Technology policy and planning in the pharmaceutical sector in the developing countries - TD/B/C.6/56 p.2

10/ Transnational corporations in the pharmaceutical industry of developing countries - ST/CTC/49 p.11

be given to establishing, with appropriate phasing, the production of certain ancillary products; packaging materials (which include vials, bottles, containers, gelatine capsules, aluminium foils and cardboard cartons); chemicals intermediates required specially for the manufacture of pharmaceutical products; and machinery and apparatus for pharmaceutical manufacture.11/

52. The table below illustrates the way in which these steps might be divided into four main phases covering the complete process of production of pharmaceuticals:-

Main phases in establishing production of pharmaceuticals and ancilliary products

Phase I	Phase II	Phase III	Phase IV
Repackaging and packaging Production of packaging material.	Formulation of tables capsules syrups ointments	Parentals injectables transfusion solutions sustained release forms	Synthetic drugs Multi-step processes Fermentation products Antibiotics Intermediates
	Production of: extracts of plant products. Organic intermediates* based on (i) petro-chemicals (ii) coal (iii) ethanol: Pharmaceutical machinery**	Biologicals Immunologicals-vaccines and sera Synthetic drugs-single-step operations Fine organic intermediates***	

* While these products belong to the chemical industry sector, attention will have to be given concurrently to setting up a basic chemical industry before any bulk drug production can take place: ideally, the establishment of production of basic chemicals should precede that of synthetic drugs and even of antibiotics.

** Some machinery and apparatus required for the production of pharmaceuticals may appropriately be manufactured by certain developing countries. This depends, however, on the stage of development reached in industrial sectors other than the chemical sector and no general guidance can be given.

*** Those that are specifically needed by the pharmaceutical industry, which it may be expedient for the pharmaceutical industry units to make for their captive use.

11/ The steps involved in establishing a pharmaceutical industry in developing countries. Report by the Second Panel of Experts on the Pharmaceutical Industry - UNIDO. ID/WG/267/3

Production Strategy

53. The presentation in the table makes it easier for the national authorities to plan step by step expansion of national production and the creation of technological capability. It is not necessary that every country should engage in all four phases of pharmaceutical production.12/ Every country should decide the scope of development of the national pharmaceutical industry in the light of its raw material resources, population size, health programmes, industrial status, technical manpower and other factors.13/

Measures for Development of the Local Industry

54. So far as countries with **advanced manufacturing capability** are concerned, it might be useful to recapitulate some of the policy measures initiated from time to time to develop the indigenous industries. Some of the approaches used by the countries are as under:

a. Nationalisation of most foreign subsidiaries, coupled with joint ventures and licensing agreements for the production of drugs or intermediates which require technologies not available locally. This approach may enable the host country to maintain the industrial property system without fear of seeing it used as a barrier to local enterprises. In Egypt, where this option was adopted, the public sector took over the industry and the Government made a major effort to create the necessary infrastructure, including the training of a large number of skilled personnel. Nationalization does not necessarily preclude continued cooperation with transnational corporations, for example, through various licensing arrangements.

b. Selective measures to regulate foreign subsidiaries and stimulate the growth of domestic enterprises; for example, Argentina, Brazil, India and Mexico adopted variations of this approach. The policies, which vary in selectivity and stringency, generally aim at minimising the extent to which operations of foreign subsidiaries can be an obstacle to the growth of domestic enterprises. Among measures taken were the following:

i. An appropriate modification of the industrial property system to increase the competitiveness of domestic firms (as in all four countries);

12/ Guidelines on technology issues in the pharmaceutical sector in the developing countries - UNCTAD/TT/49 p.22

13/ Ibid - p.22

ii. Control of the cost and restrictions of technology transfer arrangements between subsidiaries and their parent companies (as in India and Mexico);

iii. Requirement that at least some research and development facilities be established in the host country and the results be made available to domestic enterprises at reasonable cost (as in India and Mexico);

iv. Regulation of imported inputs to ensure the availability to domestic enterprises by eliminating restrictive practices or using centralized procurement to supply both foreign and domestic firms (as in India).14/

v. Requirement that foreign companies reduce their foreign equity holding (as in India).15/

55. In countries **with limited or no manufacturing facilities,** a beginning for an indigenous pharmaceutical industry may be made with the establishment of simple formulation and packaging facilities,. based on imported bulk materials. This would require less complicated facilities but still offers the possibility of achieving savings of upto 30 to 40% in foreign exchange cost of drugs. It would also establish the base for the creation of infrastructure for a more developed industry, leading ultimately to the production and processing of intermediate pharmaceuticals.16/ Given the small size of the market of these countries and the weakness of their private sector, some of them could concentrate on the development of public sector or join efforts with other countries to establish sub-regional schemes for drugs procurement and production.17/

56. The various policy measures required for promoting local industry have been shown schematically on page 26.

Concept of a 'Multi-purpose Plant'

57. In order to improve the economics of production in developing countries, UNIDO has developed a programme for the production of drugs from raw mate-

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14/ Transnational corporations in the pharmaceutical industry of developing countries - ST/CTC/49 p.63

15/ New Drug Policy 1978, Government of India

16/ Note on UNIDO activities relating to pharmaceutical production in the context of primary health programmes - UNIDO/IOD/207 - p.4

17/ Transnational corporations in the pharmaceutical industry of developing countries - ST/CTC/49 - p.64

rials or intermediates on the basis of a multipurpose plant facility.18/ This could be run economically by producing groups of drugs at a rate of 200 tonnes per year in a single unit. For example, such a multipurpose plant (under construction) is the Cuban plant, for production of 15 synthetic drugs of a total quantity of 240 tonnes per year, on technology received from India.

Utilisation of Medicinal Plants

58. The studies made by U.N. agencies highlight the importance of medicinal plants based on modern technology. A number of essential drugs used in modern medicine can be produced from medicinal plants.19/ The WHO list of essential drugs includes 30 drugs of plant origin. The developed countries which are the major importers and users of such plants process them into alkoloids and hormones etc. whereby the value of the export of the items increases as much as tenfold.

59. UNIDO has taken initiatives in arranging for transfer of technology to developing countries for utilisation of raw material (plants) for production of therapeutic agents both for export as well as for national health programmes. It has developed four types of programmes to assist the developing countries. In between 1978-83, there were 30 ongoing projects in this field and some of these were meant for strengthening the R&D institutions to develop process technology, developing technical man-power and expertise and generation and utilisation of plant raw material.

Role of Public Sector

60. The public sector has a critical role to play in starting production of essential drugs. Indeed, involvement of the public sector in the production of essential drugs is one of the options open to developing countries endeavouring to provide higher quality drugs at low cost. The drug policy of India (1978), assigns a leading role to the public sector.

61. The public sector is engaged in basic production in several developing countries e.g. in Egypt and India. In India, five Government owned companies (Indian Drugs & Pharmaceuticals Ltd., Hindustan Antibiotics Ltd., Smith Stanistreet Pharmaceuticals, Bengal Chemicals & Pharmaceuticals and Bengal Immunity) and their subsidiaries play an important role and the public sector accounts for one-fifth of the total production of bulk drugs in the country. In Indonesia, Kimia-Farma, a state-owned pharmaceutical company, produces a broad assortment of finished dosage forms from imported bulk drugs; it also produces quinine salts from indigenous raw materials and rifampicin and chloramphenicol under

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18/ Note on UNIDO activities relating to pharmaceutical products in the content of primary health programmes - UNIDO/IOD.207 p.5

19/ Report of the technical consultation on production of drugs from medicinal plants. UNIDO - ID.WG.271/6.

licence agreements with foreign companies. Cost to the consumer of finished dosage forms produced by Kimia-Farma are said to be among the lowest.20/ The public sector is deeply involved in basic production in Pakistan, where Antibiotics (Private) Ltd., a wholly-owned government enterprises, produces about 50% of the country's needs of benzyl penicillin. The Government of Pakistan also participates in joint ventures with a transnational subsidiary and owns interest in an extraction plant producing sanctonin. The Government Pharmaceutical Organisation in Thailand is a large scale producer of finished dosage forms from imported bulk drugs. It also produces inorganic salts, ampicillin and two analgesics. Small scale production of finished dosage forms is undertaken in Malaysia and Singapore by the public sector.

62. The above examples should be considered by other developing countries. It is obvious that production of essential drugs by the public sector is one of the best policy options for developing countries.

Implementation of Projects

63. Some of the major factors that have a bearing on implementation of pharmaceutical projects have been analysed by UNIDO. These are; preparation of feasibility study; effective project management team; timely allocation of funds; availability of indigenous construction materials in time, the appointment of national counterpart in projects implemented with foreign collaboration; selection of a competent engineering contractor; timely procurement of imported and indigenous equipment linked with construction schedule; availability of trained personnel and appointment of foreign experts. According to UNIDO experience, the longest delays occurred during the engineering phases in the implementation of projects and this is an area which ought to be carefully watched and all possible measures taken to avoid delays during this phase.21/, 22/

Import duty: tariff protection: protection to local industry:

64. Governments of developing countries should endeavour to enact legislation to protect the national pharmaceutical industry, to establish a system of price monitoring and to have formal or informal control on imports and tariff protection to indigenous manufacture. The duty structure should be so designed to ensure that indigenously produced drugs are not priced out of the market. The various mechanisms for such protection could be: (a) high tariffs on imports of finished products (b) lower or no tariffs on import of raw materials and bulk drugs and (c) authorisation of imports only of essential drugs that are not produced locally.

65. Once indigenous production of bulk drugs starts, duty on imported bulk drugs should be gradually raised to maintain the price differential between imported and locally-produced bulk drugs. The duty structure should be kept under constant review so that it does not stifle indigenous production.

20/ Global study of the pharmaceutical industry-ID/WG.331/6 p.95

21/ UNIDO's experience in implementing pharmaceutical projects in developing countries - UNIDO 10.570 - p.105

22/ Global study of the pharmaceutical industry - ID/WG.331 p.6

66. India has used tariff protection to great advantage to promote the indigenous industry. Finished formulations, barring a few specialised drugs such as anti-cancer drugs, are not allowed to be imported. Bulk drugs which are allowed to be imported are subjected to a basic duty of 60% advalorem plus an auxilliary duty of 40% advalorem. Intermediates are subject to basic duty of 70% plus an auxiliary duty of 40% plus a countervailing duty of 12%. Certain essential bulk drugs and intermediates which are not produced in the country are levied concessional duty or nil duty.

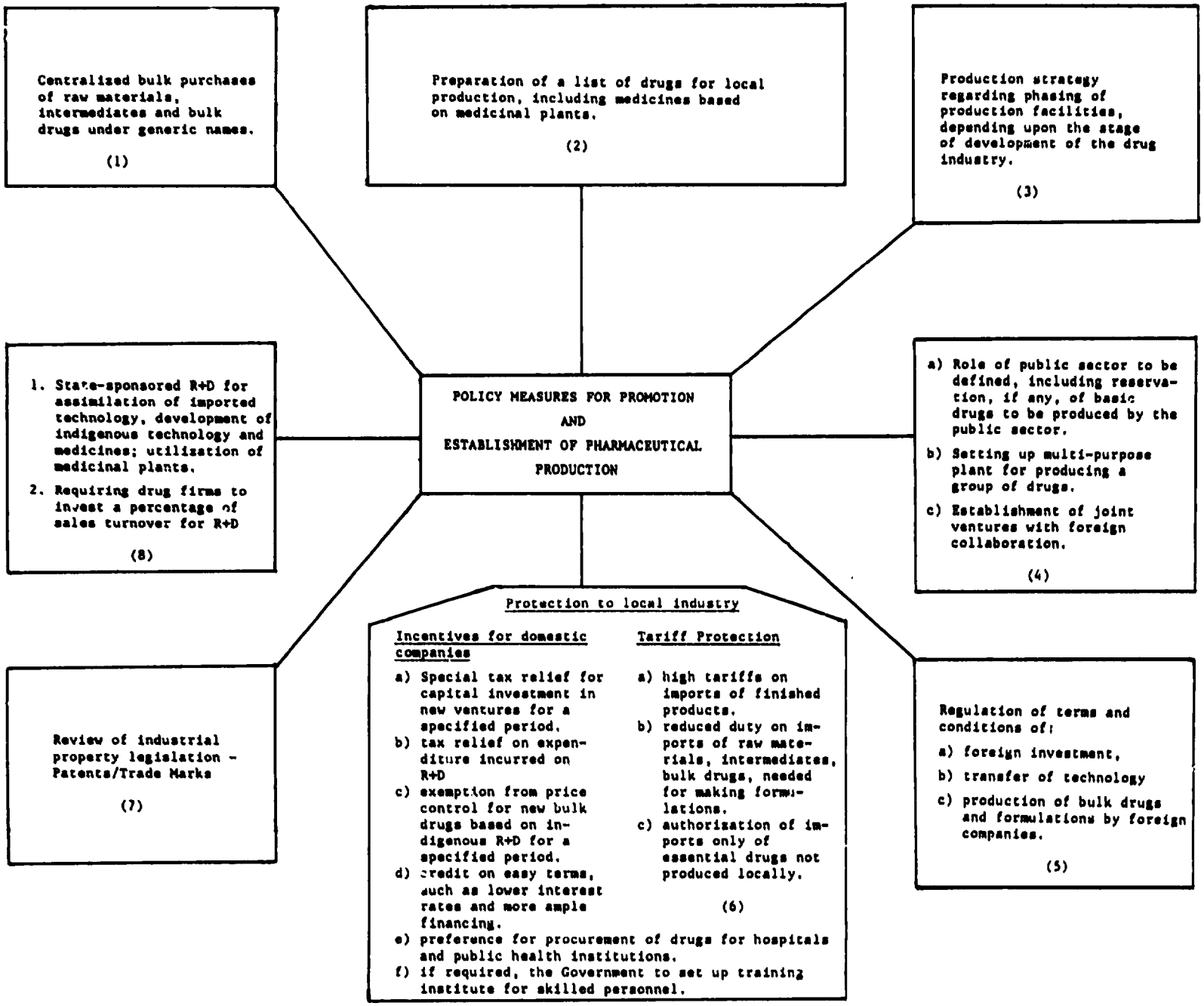
67. Case studies have revealed that several developing countries have not resorted to tariff protection to encourage indigenous manufacture even when they have some local production. In Kenya, for instance, there is no import duty on finished medicines: however, raw materials and packing materials are subject to duty. In Malaysia, duty is nominal although 20% of drugs are locally manufactured. Countries wanting to establish their own pharmaceutical industry should immediately take steps to suitably modify their import policy.

Incentives for local production

68. To generate local production of essential drugs, it may be necessary to offer special incentives to producers. Since the profits are relatively low such incentives could be in the form of (a) special tax relief (b) development rabate (c) level quotas for imports or for increased formulation capacity so that entrepreneurs would consider it remunerative to take up the production of essential drugs (d) credit on easy terms, such as lower interest rates and ample financing, and (e) state sponsored research and training of skilled personnel in sufficient numbers.23/, 24/

23/ Guidelines on technology issues in the pharmaceutical sector in developing countries UNCTAD/TT/49 - p.14

24/ Transnational corporations in the pharmaceutical industry of developing countries. ST/CTC/44 - p.54


Centralized bulk purchases of raw materials, intermediates and bulk drugs under generic names.
(1)
Preparation of a list of drugs for local production, including medicines based on medicinal plants.
(2)
Production strategy regarding phasing of production facilities, depending upon the stage of development of the drug industry.
(3)
1. State-sponsored R+D for assimilation of imported technology, development of indigenous technology and medicines; utilization of medicinal plants.
2. Requiring drug firms to invest a percentage of sales turnover for R+D
(8)
POLICY MEASURES FOR PROMOTION AND ESTABLISHMENT OF PHARMACEUTICAL PRODUCTION
a) Role of public sector to be defined, including reservation, if any, of basic drugs to be produced by the public sector.
b) Setting up multi-purpose plant for producing a group of drugs.
c) Establishment of joint ventures with foreign collaboration.
(4)
Review of industrial property legislation - Patents/Trade Marks
(7)
Protection to local industry
Incentives for domestic companies
a) Special tax relief for capital investment in new ventures for a specified period.
b) tax relief on expenditure incurred on R+D
c) exemption from price control for new bulk drugs based on indigenous R+D for a specified period.
d) credit on easy terms, such as lower interest rates and more ample financing.
Tariff Protection
a) high tariffs on imports of finished products.
b) reduced duty on imports of raw materials, intermediates, bulk drugs, needed for making formulations.
c) authorization of imports only of essential drugs not produced locally.
(6)
e) preference for procurement of drugs for hospitals and public health institutions.
f) if required, the Government to set up training institute for skilled personnel.
Regulation of terms and conditions of:
a) foreign investment,
b) transfer of technology
c) production of bulk drugs and formulations by foreign companies.
(5)

Chapter VI

DEVELOPMENT AND TRANSFER OF TECHNOLOGY

69. Non-availability of technology for the manufacture of bulk drugs is perhaps the largest single constraint in the development of indigenous production of bulk drugs in developing countries. These countries experience considerable difficulty in obtaining suitable technology at reasonable prices. Some developing countries have secured technology for the production of bulk drugs but, by and large, such technology is for manufacture from intermediate stages and not from basic stages. Such limited technology transfer does not enable these countries to start basic production because, in most cases, the intermediates have to be imported at high prices.1/

Constraints in the Purchase of Technology

70. Developing countries have always had a weak bargaining position in their attempt to negotiate for securing drug technology. They are almost entirely buyers of technology and rarely sellers. As buyers they face several constraints such as (1) inability to decide what drugs to produce, (2) inadequate financial resources, (3) lack of managerial resources, (4) non-availability of skilled personnel, (5) lack of knowledge to purchase essential imported raw materials and (6) inadequate or non-existent domestic R & D infrastructure to absorb and apply the technology purchased.2/

71. Even though, of late, some of the developing countries have acquired some domestic capability in the process and production technology for pharmaceuticals, the drug technologies, by and large, are concentrated in the hands of a small number of large TNC's. Developing countries,individually and collectively, must decide to reduce this technological dependence and, at the same time, to regulate and control more effectively, technology transfer, taking into account national capabilities and needs. Countries should not accept inequitable or restrictive clauses which might directly or indirectly constitute an obstacle to the growth of the pharmaceutical industry. Governments of developing countries should therefore formulate a technology policy and evolve an appropriate administrative and regulatory framework to prohibit any such restrictive or limited clauses in collaboration on technology transfer arrangements.3/,4/

1/ Availability, terms and conditions for the transfer of technology for the manufacture of essential drugs. ID/WG.331/5 p.

2/ Global study of the pharmaceutical industry - ID/WG.331.6 & Add.1 p. 68

3/ Global study of the pharmaceutical industry - ID/WG.331.6 & Add.1 p.77

4/ Technology policies and planning for the pharmaceutical sector in developing countries TD/B/C.6/56. p.15

Technology Plan

72. Most of the developing countries who have adopted economic planning as an instrument for accelerating development, have not explicitly spelt out their technological requirements in their development plans. Though a technology plan has to be an integral part of an economic development plan, in practice however, a technology plan would have to be worked out separately, dealing with problems of technology development and the plan for development of technology.5/

Components of Technology Plan

73. A technology plan for the pharmaceutical sector would need to conform to established technology policies and to provide the sequence of steps and the time dimension within which the objectives are to be achieved. The plan should make provision for the national needs of the entire pharmaceutical sector, both immediate and long-term; it should review current production capacity and the proportion of the population reached by health delivery programmes and the gaps in coverage; it should examine the country's existing human and technical resources and the steps that can be taken to fill the gaps by a more efficient use of those resources and by the allocation in future of larger resources; it should assess the possible gains to be made through cooperation with other countries of the same region to fill some of the resources gaps, and it should investigate the need for new institutional framework to satisfy the demand for manpower and for R & D support.6/

Time Frame

74. A time-frame should be established for the execution of each of the proposals made in the plan, and estimates should be made of the finance required for carrying them into effect. The economic, social and technical advantages expected to accrue to the country by various institutions should be presented in the form of projects with clearly defined goals and time schedules, and machinery should be set up to monitor these projects. In this way, the country's total scientific manpower can be involved in the process of drawing up the plan and its implementation; in countries with meagre resources, this is the only way in which rapid progress can be achieved. The plans of developing countries have to achieve in a short time span, the progress that took several centuries elsewhere.7/

Principles to Govern Transfer of Technology

75. On the initiative of UNIDO, a meeting of experts, that was held in Morocco 1981 recommended the following principles to be kept in view while

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5/ Guidelines on technology issues in the pharmaceutical sector in developing countries - UNCTAD/TT/49 p.22

6/ Ibid - p.22

7/ Technology policies & planning for the pharmaceutical sector in the developing countries - TD/B/C.6/56 p.18

preparing a document for the benefit of parties negotiating transfer of technology agreements:

(1) TOT should contribute to the identification and solutions of economic and social problems relating to the production and use of pharmaceuticals in developing countries with an aim at substantially improving, at adequate costs and quality, the availability of essential drugs in developing countries.

(2) the parties to the TOT agreement should be responsive to the health, drug, industrial and other relevant policies of the receiving country, including import substitution, development of technical skills, promotion of local innovation etc.

(3) licencing agreements should contain fair and responsive terms and conditions; including payments and be no less favourable for the receipient than the terms and conditions usually applied by the supplier or other reliable sources for similar technologies under similar circumstances.

(4) the agreement should, in principle:

(a) ensure the absorption of technology transferred by the local personnel.

(b) allow the use, as far as possible, of locally available materials and services.

(c) facilitate and in any case, do not restrict the adaptation and further development of technology received.

(d) include adequate guarantees for the performance of the parties obligations.

(e) provide full information on the characteristics of the technology and drugs to be manufactured, specially in respect of possible hazards and side effects.

(f) do not contain unjustified restraints on the receipients use of technology.8/

Contractual Arrangements for Transfer of Technology

76. The negotiating capabilities of the developing countries will be enhanced for concluding agreements for transfer of technology on fair and equitable terms if they have legal knowledge of the various contractual conditions and variations thereof (including background/explanatory notes) relating to contractual arrangements for the transfer of technology. In this context, the UNIDO, keeping in view the recommendations made by the First and Second Consultations on the Pharmaceutical Industry (held in Lisbon 1980 and Budapest, Hungary, 1983 respec-

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8/ Report of the round table meeting on development of the pharmaceutical industry - UNIDO/PC/33 p.6/7

tively), took, a concrete and useful step by preparing three important documents, relating to contractual agreements for the transfer of technology. These are:

a. "Items which could be incorporated in contractual agreements, for the transfer of technology, for the manufacture of those bulk drugs/intermediates, included in UNIDO's illustrative list."9/

b. "Items which would be included in contractual agreements for the setting up of a plant for the production of bulk/intermediates included in UNIDO illustrative list."10/

c. "Items which could be included in licencing arrangements for the transfer of technology for the formulation of pharmaceutical dosage forms."11/

77. These documents which have been prepared, keeping in view the principles for transfer of technology recommended by the experts in the Morocco meeting, provide general guidelines and drafting proposals for the negotiation and conclusion of contracts for the (a) transfer of technology for the production of bulk drugs or intermediates (b) setting up of a plant for the production of bulk/intermediates and (c) licensing arrangements for the formulation of pharmaceutical dosage forms.

78. In additions to the three documents mentioned above, UNIDO is currently engaged in the preparation of the following three documents:

(1) Items which could be included in the contractual arrangements for the setting up a turn-key plant for the production of bulk drugs/intermediates included in UNIDO List.

(2) Items which could be included in the contractual arrangements for the setting up of a turn-key plant for the formulation of pharmaceutical forms, and

(3) Items which could be included in contractual arrangements for technical assistance for the formulation of pharmaceutical forms.

Directory of Sources of Supply

79. The high prices of bulk drugs (pharmaceutical chemicals) and fluctuations in prices has a direct impact on the prices of pharmaceutical dosage forms which, in turn adversely affects the ability of developing countries to provide pharmaceutical drugs at reasonable prices to the majority of their population.

9/ ID/WG.393/1, REv. 2 (1985)

10/ ID/WG.343/4, Rev. 2 (1985)

11/ ID/WG.393/3, Rev. 2 (1985)

In order, therefore, to enhance their negotiating capacity to procure pharmaceutical chemicals from global sources of supply at reasonable prices, UNIDO, in pursuance of a recommendation made in this behalf by the Second Consultation on the Pharmaceutical Industry has prepared a 'Directory of Sources of Supply of Pharmaceutical Chemicals, their Intermediates and some Raw Materials included in the UNIDO List'. This is a valuable reference source of pharmaceutical chemicals.12/

Regulatory Framework

80. The devising of an appropriate regulatory framework and its administration is a critical link between the results of international negotiations and the fulfilment of specific national technological needs. This will ensure that when technology transfer is negotiated, an up-to-date and cost effective technology is available to ensure optimum production at a cost that allows production at internationally competitive prices to the extent possible. One way would be, as was done in India, to appoint an inter-ministerial committee to supervise technology transfers and screen applications for industrial licences in the light of clear guidelines.13/

81. Transfer of technology is closely linked to foreign investment. Most of the technology transfer to developing countries occurs between foreign parent companies and subsidiaries or affiliates operating in developing countries. Policies should be evolved spelling out clearly the role of foreign investment in the pharma sector, the scope of its activities and the relationship between parent companies and subsidiaries. Many developing countries have gradually changed from relying predominantly on private direct foreign investment to greater use of joint ventures, independent licensing and other collaborative agreements. This trend has to be accelerated and all encouragement and assistance provided for the purpose.14/

Options for Developing Countries

82. The options for developing countries are:-

(1) Foreign investment could be allowed in the form of joint ventures with domestic companies and on clearly defined terms.

(2) Foreign investment in formulation production could be made conditional on production of the active ingredients in bulk, from basic stages in a phased manner.

(3) Foreign firms may be prohibited from producing house-hold remedies but permitted to manufacture essential drugs and/or drug for more serious conditions which require sophisticated technology. For example an UNCTAD study recommended that while it would be necessary and expedient in some cases to

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12/ UNIDO/ID/WG.393/2/Rev.1 (1984)

13/ Technology policies and planning for the pharmaceutical sector in developing countries - TD/B/C.5/56 p.16

14/ Ibid - p.16

allow multinational corporations to have production units in the Caribbean region, the terms and conditions of their operation should be regulated in a harmonised manner throughout the countries of the region. Such conditions could include: (a) transnational's local production should be linked with export possibilities; (b) their production programmes should be based on a phased plans over a specified period for backward integration, leading to production of basic ingredients; and (c) production should be of essential drugs.15/

Transfer of Technology from Advanced Developing Countries

83. The studies have confirmed that the current dependence of developing countries on import of technology from developed countries can be reduced to the minimum if countries in Asia, Africa and Latin America which have technical capability in pharmaceutical production assist less developed countries in the region. They can also pool their resources, capabilities and experience for planning large scale industry in the region.

84. In fact, technology for producing the entire range of pharmaceutical formulations is available with the developing countries. About a dozen countries are engaged in the manufacture of bulk drugs which require more complex, sophisticated technology involving multi-step or continous processes. No less than 150 of the 250 essential drugs identified by WHO are produced in these countries. India and China have made considerable progress in the field of basic drugs, contraceptives and utilisation of medicinal plants. India manufactures indigenously about 225 bulk drugs, most of them essential drugs.

Cooperation in R & D

85. Better flow of technology by itself will not resolve the problem of technological dependence of the developing countries. Acquisition of technology is no substitute for indigenous research and development (R&D) efforts. The recipient country should be able to assimilate and improve upon the imported technology through its own R&D facilities. Since patents for most of the essential drugs have expired, these can be manufactured without legal complications provided indigenous R&D efforts are capable of developing manufacturing process for them. In this context, technical cooperation among the developing countries in promoting R&D facilities in countries which do not possess the same at present is desirable. Such cooperation makes it possible to draw up a common R&D plan, avoid duplication of efforts and promotes free exchange of scientific information among the developing countries.16/

15/ Report & recommendations of the workshop on trade and technology policies in the pharmaceutical sector in Caribbean Region-UNCTAD/TT/Rev.1 p.15

16/ Technical cooperation among developing countries in the field of pharmaceutical industry, ID/WG.331/6/Add 1 p.5

Chap VII

RESEARCH & DEVELOPMENT

Present Position of R&D in Developing Countries

86. It is most important that the establishment of pharmaceutical industry in a developing country should be backed by research and development (R&D) activity. It is only with this backing that the national industry can grow properly, imported technology can be assimilated and new technology can be developed. This is particularly true of an industry so heavily dependent on research as the manufacture of pharmaceutical products. A research base is the insurance against future backwardness and under-development.

87. In most developed countries, research in this area is carried out by the pharmaceutical companies. Since, there is little or no national industry in this field, in many developing countries, the initiative in promoting research and development, has to be taken by Government, by setting up research institutes or by providing encouragement and incentives to pharmaceutical companies, to undertake research. Where Government has taken the initiatives, the results have been all positive. The indigenous R&D activities are lacking in most of the developing countries. However, some of the developing countries have undertaken appreciable R&D efforts owing to the considerable progress made in the development of the pharmaceutical industry, and the infrastructure available for undertaking research. However, due to the inherent constraints involved in basic research, major effort in this area has been limited to development work, rather than basic research. Some developing countries in which R&D facilities and capabilities are available, include India, Argentina, Bangladesh, Brazil, Egypt, Korea, Mexico, Iraq, Pakistan, Cuba and Costa Rica. R&D on medicinal plants is also carried out in some of these countries. The research and development activities are undertaken by (a) Government Research Institutes, (b) transnational corporations or (c) R&D sponsored by international organisations.1/ to 5/

1/ Technological policies in the pharmaceutical sector in Venezuela UNCTAD/TT/25 - p.28

2/ Technology policies in the pharmaceutical sector in the United Republic of Tanzania. UNCTAD/TT/85 - p.24

3/ Technology policies in the pharmaceutical sector in the Phillipines. UNCTAD/TT/36 p.9

4/ Report and recommendations of the workshop on trade and technology policies in the pharmaceutical sector (Abidjan, Ivory Coast) UNCTAD/TT/35 p.9

5/ Global study of the pharmaceutical industry, ID/WG.331.6 & Add1 p.84-85

Objectives

88. It is essential to ensure that the meagre resources available are optimally utilised. R & D in developing countries should be directed towards predetermined goals and objectives that reflect national priorities and needs. It is important to define the priorities and goals and to identify the problems carefully. To achieve these goals both basic and applied research will be needed.6/

89. In view of the scarcity of the requisite manpower and facilities, the small volume of the total research effort and the low research capability in most developing countries, there should be proper coordination of research committee set up within the Ministry of Health or Industry or through an autonomous research council. This body should act as the nodal agency for coordinating activities in national pharmacy, hospitals and medical colleges. Such coordination would help to avoid unnecessary duplication of research and also make the academic community aware of the country's problems and needs, enabling it to identify relevant areas and direct research accordingly. Such coordination should not be limited to research within a country but should be extended to different countries in a particular region so that there is no duplication of research effort undertaken by different countries.

Priority Areas

90. The areas that need priority attention are:

(1) development of pharmaceutical technology covering, interalia, process improvement, formulation development and import substitution,

(2) development of new drugs for tropical diseases and

(3) traditional medicine, particularly, identification, extraction, and purification of active ingredients from plant materials and studying their biochemical properties.7/

91. So far as development of pharmaceutical technology is concerned, it would be best to set up a separate research institute or a department, within a drug research institute, to initiate the development of major activity. The institute would be closely involved in the setting up of manufacturing operations right from the beginning. Its main task would be the assimilation and improvement of technology acquired by the industry. The research priorities of such an institute would be determined by the needs of the industry in terms of its immediate production programme and the country's long term needs. Experience shows, that where Government has taken the initiative and set up research institutes, the results have been quite encouraging.

6/ Technology policies & planning for the pharmaceutical sector in developing countries. TD/B/C.6/56 - p.25

7/ Ibid p.26-27.

92. So far as the research for new drug development is concerned, it would be useful to develop research capability in the country. Research could be carried out both in the development of new drugs, and in the processing technology, for the manufacture of pharmaceutical products. The priority research areas would be:

(a) investigation of traditional remedies,

(b) biological screening of terrestrial plants and marine flora and fauna,

(c) new drugs and methods of control of special importance, under local conditions, such as drugs for the treatment of tropical diseases, communicable and parastic diseases and fertility control.

93. As regards research in traditional medicine, research would be directed towards the identification, extraction and purification of active ingredients from plant materials and studying their biological properties.

Funding of R & D

94. So far, as funding is concerned, Government extends budgetary support to institutes directly under its administrative control. It may also sponsor research through private research institutes and fund the programmes. So far, as the industry is concerned, a measure that has been suggested, is to make it obligatory for the pharmaceutical firms to set aside a certain percentage of their turnover for R & D. Under India's Drug Policy (1978), foreign companies, whose drugs turnover exceeds Rs.50 million per annum are obliged to invest at least 20% of the net block for R & D within the country, and to spend a minimum of 4% of their sales turnover as recurring expenditure on R & D. The policy exempts from price control, for 5 years, new bulk drugs, not produced elsewhere, but developed through indigenous R & D. A higher gross profit, ranging from 10 to 30%, related to sales turnover, is admissible to those manufacturers who are having basic drug manufacturing activity and are engaged in approved research and development work, relating to new drugs.

Scope for Regional and International Co-operation in R & D

95. Since many countries in a region face similar health problems, there is scope for co-ordinating R & D efforts, on the regional production of drugs of vegetable origin, manufacturing processes, and research on medicinal plants. Countries in the Caribbean, Asia and Latin America, could co-ordinate research activities. In this context, it may be mentioned that the Second Consultation of the Pharmaceutical Industry, agreed that UNIDO might, at the request of interested Governments, undertake a feasibility study and subsequently convene another inter-Governmental meeting, to consider the establishment of a process research and development centre (to be financed from funds available to the interested Governments), which, inter-alia, would provide services to interested countries in acquiring and assessing technologies for the pharmaceutical sector,

development of manufacturing processes, to fit their specific needs, provide reference quality control for raw materials, intermediates and bulk drugs, assist in development of medicinal plant industry and organise training courses.8/

8/ Second Consultation on the Pharmaceutical Industry (1983) - ID/WG-393/19 p.9

Chapter VIII

INDUSTRIAL PROPERTY LAW: PATENTS AND TRADE MARKS

Patents

96. Pharmaceutical industry is a major industry in which protection granted for innovation through patents has played a significant role.1/ Patents of products and processes are common in many countries. Limiting them only to process claim, has the advantage that it could facilitate further innovations through alternative routes to produce the same product. Coverage of patents to products per se is likely to inhibit the innovation through alternative routes and tends to create monopolies. Much of the claims made for the patent system (that it acts as an incentive for innovation, facilitates transfer of technology, etc.) have no relevance for the developing countries which have neither the infrastructure nor the resources for undertaking research leading to the discovery of new drugs. A fundamental reassessment and revision of the industrial property system, as it exists in the developing countries, is urgently needed.2/ Patent law for the pharmaceutical sector needs to be tailored to suit the needs of this sector in each country.3/

97. In order to ensure that the protection granted through a patent system finally benefits the society, it is necessary that the patents are actually worked. Abuse of patents arising from the failure to work is dealt with in most of the patent systems through the provisions of compulsory licenses. Experience in the grant of compulsory licence has shown that very long delays are involved. To facilitate the use of inventions easily, India has also provided for "Licence of Right". Patents which are marked with these words could be commercialised even in the absence of a compulsory licence in which a pre-determined compensation would, however, be paid to the patent holder.

98. The protection granted to a patent is limited in time. This generally varies upto 20 years. For example, the fees payable in India for maintaining a patent per year is more in the later years since it is expected that lower fees in the early years will facilitate more ready disclosures. This is also a recognition of the fact that all patents granted are likely to find commercial utilisation.

99. There are two options for the developing countries in this regard:-

(1) Patents may be abolished for both pharmaceutical products and processes.

1/ The role of the patent system in the transfer of technology to developing countries, prepared jointly by UN Department of Economic & Social Affairs, -UNCTAD & WIPO-TD//AC.11/19/Rev.1 p.282

2/ Technology policies & planning for the pharmaceutical sector in developing countries - TD/B/C.6/56 p.13

3/ Ibid. p.13

(2) Patent protection may be limited to processes only; adequate safeguards may be prescribed to ensure satisfactory working of the patented inventions. The safeguards may be: (a) specify that importation does not constitute working of the patent. (b) provide for an expeditious system of compulsory licensing (c) use forfeiture or revocation of the patent on specific grounds (d) shorten the duration of the patent and use it to ensure satisfactory working of the patented invention.4/

Trade Marks (Brand Names)

100. Product differentiation has been used by pharmaceutical enterprises as one of the means to achieve market power. Trade marks and brand specific advertising are basic means used to differentiate products in the industry and have been extensively applied in the marketing policies of pharmaceutical firms. It has been estimated that more than 40 per cent of the trade marks used throughout the world relate to pharmaceuticals and associated goods. Trade marks are the basis of brand competition, which predominates over price competition in this industry.5/

101. Brand names have a very restrictive effect on the development of the pharmaceutical industry. The various studies made relating to both developed and developing countries have shown that purchase of drugs under generic names results in substantial savings. The PARCOST (Prescription at Reasonable Cost) system in Canada and the experience of the U.S. FDA show that on the one hand, price stability can be maintained for good drugs and inspection of manufacturing processes can be facilitated by means of a comparative index of drugs showing price, manufacturing cost, composition and characteristics and, on the other hand, buying by generic names makes possible considerable savings.6/ In many States in the U.S.A. the law requires or permits pharmacists to substantiate generic equivalents for drugs prescribed by brand name provided the quality of the former is guaranteed by the Food & Drug Administration which has for this purpose published a list of "Approved Prescription Drug product with Therapeutic Equivalence Evaluations". The list originally contained 5,000 prescriptions drugs approved by FDA as safe and effective. The objective of preparing the list was to assist Governments and institutions. (hospitals) in purchasing and dispensing drugs by generic names to reduce cost and has been called a milestone in Government efforts to lower the cost of health care.

102. Among developing countries, Pakistan banned brand name for drugs by the Drugs Act, 1972 but after serious difficulties had arisen in quality control, the Act was repealed and legislation enacted in 1976 which allowed some use of brand name. Sri Lanka introduced generic nomenclature without changing the trade mark law. When the State Pharmaceutical Corporation of Sri Lanka

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4/ Global Study of the pharmaceutical industry - ID/WG.331/6 p.49

5/ Guidelines in technology issues in the pharmaceutical sector in the developing countries-UNCTAD/TT 49 p.10.

6/ Report and recommendations of the workshop on trade and technology policies in the pharmaceutical sector in the Caribbean Region-UNCTAD/TT/41/Rev.1 p.7.

was made the sole importer of pharmaceuticals it purchased drugs under generic names and effected substantial savings in cost.7/

103. In 1978, Indian drug policy prohibited brand names for five drugs(analgin, aspirin, chlorpromazine, ferrous sulphate and piperazine and its salts); single ingredient dosage forms of these drugs are required to be marketed only under generic names. The policy also required the Drugs Controller not to recognise brand names of single ingredient new drugs which shall not be allowed to be marketed under brand name when first introduced into the country.8/

104. Doctors often resist generic prescribing because the brand names are more familiar and tend to be easier to remember. The pharmaceutical industry's main argument against generic prescribing is that the brand name guarantees the quality of the product, since a large and reputable company would be less likely to market substandard drugs. But brand names do not necessarily assure quality. The United States Food and Drug Administration has shown that branded and generic products have been substandard with about equal frequency. A non-branded product from a reliable firm is as likely to be effective as a branded product.9/

105. Generic equivalents are usually much cheaper than the corresponding branded drugs. For example, the Drug Benefit Formulary, No.13 of the Ministry of Health, Ontario, Canada. effective 1 July 1980, indicates that generic diazepam is 10 times cheaper than the branded equivalent "Valium."10/

106. The simplest solution to the problem is to forbid the use of brand names. In some countries, however, this may not be practicable, and an alternative is to require the use of generic names together with that of brand names. Regulations could be issued requiring the generic name to be printed on all labels and promotional material more prominently and/or in large type than the brand name, and preceding it.11/ Recently, the Government of India decided that generic names should be printed in double the size of brand names.12/

107. It is essential to have a reliable system of quality control or assurance if generic names are to be established in place of brand names. An attempt to introduce generic names without adequate quality assurance has sometimes failed, as in Pakistan, because interested parties can adduce the poor quality of certain non-proprietary preparations as a strong point against such a policy.13/

7/ Case studies in transfer of technology: pharmaceutical policies in Sri Lanka-TD/B/C.6/21 p.3

8/ New Drug Policy, 1978, Ministry of Chemicals and Fertilizers, Government of India.

9/ Guidelines on technology issues in the pharmaceutical sector in the developing countries-UNCTAD/TT/49. p.13

10/ Ibid. p-10.

11/ Ibid. p.10

12/ Circular letter from Drugs Controller (India)

13/ Guidelines on technology issues in the pharmaceutical sector in the developing contries-UNCTAD/TT/49 p.13.

Generic Policy and Medical Profession

108. It must be emphasised that a generic policy cannot succeed unless doctors are encouraged to prescribe by generic name. It is, therefore, essential that representatives of professional bodies of doctors are actively associated with the formulation and implementation of the generic policy. Commitment of the medical professional is basic to the success of any generic programme. They should evolve their own work ethics and code of conduct and prescription by generic name should be part of that commitment. Government and voluntary medical/health organisations have a responsibility to educate doctors about the cost aspects of generic prescription. For the majority of patients in developing countries the choice is not really between branded drugs or generic drugs but between treatment with cheaper generic drugs or no treatment at all. It is, therefore, an important part of the professional obligation of doctors to prescribe cheaper generic drugs for their poor patients where such drugs are available.

109. The case for the substitution of brand names by generic names is thus strong, although the issues involved in the implementation of such a policy are complex. They are related to the structure and degree of degree of development of the pharmaceutical industry, the role played by public enterprises and affiliates of transnational corporations, the prescribing habits of the doctors and the effectiveness of the drugs control machinery.14/

14/ Technology policies and planning in the pharmaceutical sector in the developing countries-TD/B/C.6/56 p.14.

Chapter IX

TRANSNATIONAL CORPORATIONS IN DEVELOPING COUNTRIES

110. Transnational Corporations (TNC's) play an important role in the pharmaceutical industry of developing countries. Even in the most developed of the developing countries where local production can satisfy most of the local demand, TNC's continue to occupy a leading position through direct investment, joint ventures and licensing agreements and as a supplier of technology and process know for several important essential drugs.1/

111. What are the implications of the operations of TNC's in developing countries? While the countries realise the contribution made by TNC's in producing many essential drugs, their fears stem from the past record of the TNC's in developing countries owing to their dominant position and the power they wield with a strong bargaining position.

Domination of Market by TNC's

112. Reports indicate several ways in which TNC's dominate the market in developing countries. Among them are (1) withholding of technology for the manufacture of drugs and forcing developing countries to import finished formulations (2) supply of technology for the local manufacture of formulations only and compelling developing countries to import bulk drugs at high prices, (3) introducing restrictive clauses in technology agreements which prevent the purchaser from exporting products manufactured by using the technology, (4) insisting that any improvements made in the technology is the property of the supplier or charging the purchaser high fees for improvements made by the supplier while the agreement is still in force, (5) supplying technologies that became obsolete and was discarded by the supplier, (6) charging widely varying prices to different countries for the same technology, (7) indulge in transfer pricing, (8) supplying products that are harmful or that are not approved in the country of origin, (9) excessive promotion using brand names of unnecessary drugs, (10) overcharging the consumer, (11) marketing drugs without adequate warning about side effects and precautions and for indications different from those approved in developed countries, (12) indulging in unfair competition to suppress local competitors.

Concerns of Developing Countries

113. From the foregoing it is obvious that the concerns of many developing countries regarding TNC's pertain to a number of social, economic and technical

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1/ Transnational operations in the pharmaceutical industry of developing countries ST/CTC/49 p.9

issues. First, the cost of drugs. This has been a major concern to developing countries in view of the scarcity of their financial resources. These countries are interested in reducing that cost, particularly in the case of branded products, by seeking alternative procurement methods, multiple-source of supply and a more effective regulation of pricing of pharmaceutical products.A major challenge in this respect is to ensure that the search for less expensive drugs does not lead to lower quality. Second, marketing practices. Developing countries are concerned about these as they lead to proliferation of branded drugs. An important issue in this respect is the role of patents and trade marks used by TNC's to multiply the number of drugs and control markets. Marketing practices also raise questions about the appropriateness, efficacy and safety of certain drugs. Third, local production. Many developing countries have attempted, with varyng degrees of success, to establish local production facilities in the hope of decreasing the cost of drugs, increasing self-sufficiency and enhancing their industrial development. The activities of some TNC's can be seen as presenting obstacles to indigenous efforts. Others, however, are credited with having supported such efforts.2/

Technology Transfer

114. Technology is a major strength of the TNC's. While it is jealously guarded by most companies, a beginning is no doubt being made in some countries to ensure the transfer of technology without restrictive or unfair clauses relating to licensing of patents, trade marks and know-how, export markets or sources of supply of raw materials, intermediates, capital goods and spare parts, research and training of local personnel in research and development, transfer of equipment purchased for R+D to the parent company.

Measures to Regulate Practices of TNC's

115. The study by the UNCTC has described the activities of the TNC's in the areas of marketing and promotion, drug prices, and technology and R&D and national health policies and priorities. These have been referred to in the relevant preceding chapters. The various measures required to regulate the activities of TNC's in these areas have also been listed at the appropriate chapters. Suffice it to emphasise here that there are no soft options open to developing countries. The solution lies in building up their own capabilities in the pharmaceutical sector by urgent and decisive action by the developing countries themselves individually and as a group by mutual cooperation at sub-regional, regional and international levels. The steps already taken or recommended to be taken in this regard have been discussed in the preceding chapters. To recapitulate:

1. Developing countries must develop individually and collectively their technological capabilities to meet their health and drug needs.

2/ Transnational Corporations in the pharmaceutical industry of developing countries ST/CTC/49 p.10.

2. Regulate the terms and conditions of transfer of technology by suitable legislative or administrative action.

3. Require TNC's to establish R&D facilities in the host country.

4. Develop their pharmaceutical industry both in the public and private sectors.

5. Introduce price control or price surveillance and strict control on import.

6. Introduce a system of centralised purchasing of imported drugs.

7. Curb excessive promotion and unethical marketing practices.

8. Restrict patents and curtail the use of brand name and promote generic names.

9. Introduce a system of legal and administrative control on the quality of imported and indigenously produced drugs.

10. Examine possibilities of indigenising the ownership patterns of TNC's. In India, the Foreign Exchange Regulation Act (FERA) and the Drug Policy provide for fixation of the permissible level of foreign equity on the basis of whether or not the firms manufacture high technology bulk drugs and intermediates. As a result of the implementation of this provision the number of foreign companies (i.e. companies with foreign equity above 40%) have declined from 31 at the time of the drug policy in 1978 to 10 at the end of 1985. More are expected to Indianise in the coming years.

11. To sum up, the national development of the whole system of procurement, production and distribution of pharmaceuticals linking the nation's health needs seems to be only feasible way of achieving the aim of checking and monitoring the practices of TNC's.3/

116. It is widely recognised that the TNC's by virtue of their enormous resources and technological skills can make a significant contribution to the developing countries urgent need to improve the health care of their population. Such a contribution can take a variety of forms such as reallocation of research and development resources in favour of the major tropical diseases, manufacture and sale of low-priced essential drugs and the provision of the necessary technology under reasonable conditions for the manufacture of essential drugs. Some firms are already moving in that direction, but their efforts remain limited compared to the resources of the worldwide industry and to the enormous needs of the developing world.4/

3/ Major issues in the transfer of technology to developing countries-TD/B/C/6/4 p.50

4/ TNC's in the pharmaceutical industry of developing countries-ST/CTC/49 p.9

117. Developing countries recognise the importance of research-oriented companies, domestic or international, but would require them to operate in conformity with national priorities and policies. If the companies do so, they are bound to be given a role in any national, regional or international strategy for providing better health care to peoples in developing countries. Since governments of developing countries have to strike a balance between national policies and international business realities in the quest for and use of essential pharmaceuticals, those TNC's that can identify themselves with the host country's aspirations and goals and adapt and attune their business policies to the larger national objectives would have a role to play in the current and emerging socio-economic environment of the developing countries.

Chapter X

PRICING OF DRUGS

118. An important element of drug policy is the regulation of drug prices. In practice, the drug industry has been in general among those with the highest profit margins. Owing to the dominant position of transnational corporations in most markets in developing countries, three sorts of price differentials in the drug industry have been noticed. These are:-

a. **Price differentials between parts of the same country or different purchasers.** e.g. the same brand of drug may be sold to different buyers at varying prices in the same country.

b. **Price difference between countries:** In such a situation, the same product may be sold at vastly differing prices by the same firm to different countries.

c. **Price difference between brand names and generically named equivalent products:** In this situation, there are large price differentials betwen products sold by brand names and those sold under their pharmaceutical generic names. The prices of brand named drugs may have little relation to their cost of production or to prices charged by smaller competitors.1/

Price Regulation

119. Against this background it was obvious that Governments of developing countries for political, economic and social considerations would initiate measures to introduce some sort of product and price regulation to provide for consumer protection, ensure supplies of both imported and indigenous drugs at fair prices, generate greater emphasis on production and supply of essential drugs, protect the local industry from unfair competition resulting from practices of transnational companies and from international market forces.2/ The policies followed in this regard may vary from country to country depending upon the stage of development of the drug industry, the political system of Government and the character of the market system.

1/ Major issues in transfer technology to developing countries - A case study of the pharmaceutical Industry - TD/B/C.6/4 p.27

2/ Guidelines on technology issues in the pharmaceutical sector in the developing countries - UNCTAD/TT/49 p.17

Policies of Price Control

120. The various policies followed in this regard in various countries is briefly described below:

International Dimension

a. **Countries with advanced manufacturing capability**

For these countries, the price issue concerns mainly the importation of raw materials, particularly intermediate chemicals, which are often subject to transfer pricing. The following policies have been tried with mixed results:

i. Imposition of ceilings on the prices of imported intermediates;

ii. Checking declared prices against reference prices, if available;

iii. Exchange of information on such prices among home and host countries.

121. Ultimately, transfer pricing is difficult to monitor and control since intermediate chemicals are highly firm and product-specific. The imposition of ceilings on their import prices is likely to be arbitrary and ineffective.

122. From the viewpoint of developing countries one solution would probably be to increase the production of their own intermediates through greater backward integration of their pharmaceutical industries. But this should be done only if certain pre-requisites are met and after the trade-offs between local production and imports have been carefully assessed.3/

b. **Countries with some manufacturing capabilities**

Countries where local production is limited to formulation and packaging and where foreign firms play a dominant role are faced with the problem of monitoring and controlling the prices of imported finished and semi-finished drugs, particularly in the case of intra-firm transactions. There has been a clear trend toward more effective price controls for the public sector, leaving the private sector under less regulation. The following policies seem particularly worth noting for the public sector:

i. Checking import prices against readily available reference prices;

ii. Selection of imported drugs in bulk form, through a national list of essential drugs.

iii. Procurement of imported drugs in bulk form, through public tendering, under generic names when possible.

3/ Transnational corporations in the pharmaceutical industry of developing countries - ST/CTC/49 p.60

c. **Countries with little or no manufacturing capabilities**

Given their high dependence on imported finished drugs, the same policies may also be applicable to these countries. In addition due to the small size of their markets, they may be able to benefit from joint procurement institutions, particularly at the sub-regional level.

Domestic Prices

123. The problem of checking the domestic prices of pharmaceuticals is common to all developing and many industrialised countries, regardless of the level of development of their pharmaceutical industries.

124. Among the policies adopted by the countries surveyed, the following seem particularly worth noting:

a. Use of standard formulae applicable to all drugs, based on the cost of production or landed cost in the case of imports and an appropriate profit margin;

b. Implementation of price controls through administrative procedures;

c. Provision of a mechanism for a periodic review of prices to allow increases when justified and to prevent the registration of "similars" mainly intended for charging higher prices;

d. Use of two or three-tiered pricing mechanisms to distinguish between the prices of basic drugs (according to an essential drugs list) and other drugs or among various markets or consumers (lower prices for low income groups, for example) with subsidization of the lower prices if necessary;

e. Special treatment of the prices of drugs resulting from demonstrated research and development activities by a given firm, e.g. temporary exemption from price controls for specified periods.4/

System of Price Control in Some Countries

125. The problem of controlling the domestic prices of pharmaceuticals is common to all developing countries and many developed countries as well, regardless of the level of development of their pharmaceutical industries. Some form of price regulation or control exists in most developed countries. In some

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4/ Transnational corporations in the pharmaceutical industry of developing countries - ST/CTC/49 p.63

countries, however, such as Switzerland, West Germany and Japan, Government does not regulate prices and competition among manufacturers and the economic law of demand and supply ensures effective control over drug prices.5/ On the other hand, there are other developed countries such as Sweden, UK and Italy, where some form of price control prevails.

126. In Sweden, price control on pharmaceuticals is an integral part of the Government drug policy.6/ The Swedish Pharmacies are run by the Government dominated National Corporation of Swedish Pharmacies and it is a requirement that the sale price should be fixed by negotiations between the Corporation and the applying manufacturing company. this is deemed to be reasonable provided there are no special reasons to the contrary. If agreement cannot be attained, the drug company can take the case further to the National Board of Health and Welfare for decision. When agreement is reached on the prices it is often understood that it is based on the assumption of a certain sales volume and that new negotiations should be initiated if that volume is exceeded. A perusal with prices in other countries and changes in volume is an important criterion kept in view.

127. In UK, the comprehensive health scheme financed by the Department of Health and Social Security covers about 170 to 180 pharmaceutical manufacturers and suppliers. The price system is not covered by statutory regulations but is based on a voluntary arrangement of understanding between DHSS and the pharmaceutical industry.7/ As a general guide the profitability of UK industry as a whole is taken into account. In 1983, broadly speaking, a 20% return on invested caspital or 10% profit on sales was considered reasonable. In the event, companies profit level is found to be excessive the DHSS may require prices to be reduced during the trading year to the point where profits are bought in line; or in some circumstances repayment to the Department of excess profits which were generated in the precedilng year. it may be mentioned that one of the objectives in building up the control system has been to establish an effective control of prices and profits with the minimum level of bureaucracy and at the lowest operating cost to Government. In Italy, the manufacturers usually fix the sale price to the consumers according to certain established rules. The price fixation is based on the cost of raw materials, cost of packing materials and the manufacturing expenses. A multiple of the cost is used to arrive at the consumer price. The multiplying factor is at a higher rate for research based companies.8/

5/ Indian pharmaceutical industry - problems & prospectus - NCAER

6/ The need for drug policies - ID/WG.393/15 p.9

7/ Ibid - ID/WG.393/15 p.13

8/ The Indian pharmaceutical industry - problems & prospects - NCAER

128. Among the developing countries some information is available regarding the price system in force in Mexico and India. In Mexico within the price system three sets of detailed rules have been established, each applying to one of the following kinds of drugs:9/

i. finished drugs paid by the consumer;

ii. finished drugs paid by the Government;

iii. active ingredients.

129. Before a finished drug is put on the market and every time the manufacturer wants to increase the price of the product he has to present an application with comprehensive economic information to the competent authority. This information should include general data regarding the company, general data on the product and similar products, information about production, commercialisation and taxes, raw materials used, direct labour costs, other costs for manufacture, sales and administration.

130. In India, the salient features of the pricing scheme for drugs, under the new drug policy, announced by Government, in 1978 are as under:

a. All bulk drugs, which are used in the production of price controlled formulations, are subject to price control.

b. The post-tax return on bulk drugs, required for production of category I and Category II formulations, which are highly essential and life saving, is kept at 14% and on other bulk drugs, at 12% on net worth, i.e. equity plus free reserves.

c. Where the indigenous bulk drug is produced by more than one manufacturer, a common selling price for sales to all formulators is fixed, on the basis of the average costs of relatively more efficient firms which account for a large percentage of output.

d. The price control on formulations, is on a selective basis and for this purpose, four categories are established.

e. The pricing of formulations in Category I and II, is worked out on the basis of product groups of equivelent therapeutic value. Such pricing is based on the "leader product" of leading producers, whose price serve as a ceiling on all other formulations, within that group. The mark-ups are 40% and 55% respectively.

9/ The need for drug policies - ID/WG.393/15

f. So far as Category III is concerned, separate pricing for each producer is done. The mark-up for this category is a maximum of 100%, the manufacturer being free to choose his own mark-up, upto the limited ceiling.

g. In respect of Category IV, there is no price control.

h. The gross profit of the individual manufacturers is contained as follows:

	Pre-tax return on sales turnover exclusive of excise duty
i. **Large units** with turnover exceeding Rs. 6 crores per annum and	
a. having no basic drug manufacturing activity nor any research activity	8%
b. having basic drug manufacturing activity corresponding to 5% or more of turnover but no research activity	9%
c. having basic drug manufacturing activity at 5% or more of the turnover and engaged in approved research and development work relating to new drug	10%
ii. **Medium size units** with turnover between Rs. 1 crore to Rs. 6 crores per annum and	
a. having no basic drug manufacturing activity nor any research activity	9%
b. having basic drug manufacturing activity corresponding to 5% (or more) to turnover but no research activity	11%
c. having basic drug manufacturing activity at 5% or more of turnover and engaged in approved research and development work relating to new drugs.	13%
iii. **Other units** with turnover of less than Rs. 1 crore per annum	
a. having only formulation capacity	12%
b. having basic drug manufacturing activity at 5% or more turnover	13%

i. In respect of new formulations, including formulations arising from new bulk drugs, the following mark-ups are permitted:

Category I	40%	: Subject to the overall ceiling on profitability as above.
Category II	50%	
Category III	Not to exceed 100%	
Category IV	Not subject to price control.	

j. The prices of intermediates produced by the public sector undertakings are fixed by Government in consultation with the Bureau of Industrial Costs and Prices.

k. Eight critical drug intermediates namely: (a) Meta-Amino-Phenol, (b) Para-Nitro-Chlorobenzene, (c) Picolines, (d) Para-Nitro-Benzoic Acid, (e) Methyl Imidazole, (f) Dextrose, (g) Acetanilide, and (h) Ethylene Oxide, are also subject to price control. However, a return of 12-14% on net worth is assured for drug intermediates also.

l. There is no price control on bulk drugs, developed through indigenous R & D efforts and its formulations for a period of 5 years.

131. It may be stated, in passing, that while India's new drug policy has contributed considerably to the growth of the indigenous industry, given a boost to the production of bulk drugs and formulations by Indian companies and accelerated the pace of indigenisation of foreign companies, the pricing scheme has revealed practical difficulties in implementation. The industry has represented that the pricing sheme is comprehensive and inflexible, and that the administrative machinery for fixing and revisisng prices has found it difficult to cope with thousands of applications for price revision and fixation. Secondly, due to considerable delays in revision or fixation, profitability of the industry has been eroded, and this has affected its capacity to generate adequate internal resources for expansion and modernisation. The industry has, therefore, preferred a scheme of selective price control confined to essential bulk drugs and formulations based thereon, as the most practical approach to price control. The Government of India is reportedly considering the suggestion, as part of the overall review of the drug policy.

Need for Expert Body

132. Countries wanting to introduce price control on drugs should also establish the requisite administrative machinery for fixing and revising prices periodically on the basis of trends in cost of production. An expert advisory body must also be set up to undertake cost studies, (for example, in India there is the Bureau of Industrial Costs and Prices) review trends in cost of production and to advise the Government on linkage of prices to cost of production. This is a continuing exercise calling for a high degree of expertise and experience in industrial cost studies.

Chapter XI

CONTROL OVER QUALITY OF DRUGS

133. A drug policy which aims at redcucing and rationalising the use of imported drugs and lowering their costs and this applies just as much to promotion local production thereof - must have built into it proper safeguards through an effective system of quality control.1/

134. Production of drugs of assured quality and maintenance of that quality while the drugs move along the various distribution channels until they reach the patient are the responsibility of the producers and distributors (both wholesale and retail), exercised in the framework of regulatory controls formulated by Governments on a legal basis. Drug control regulations vary from very rigid sets of rules well implemented in developed countries to regulations poorly implemented in some developing countries and virtually no controls in some of the least developed countries. In some countries, there is virtually no post-market surveillance, and control of business practices is lax, reflecting the limited financial, technological and human resources of those countries. Under these conditions, in many developing countries, there is no mechanism to prevent unscrupulous "dumping" of drugs. Hence efforts should be made at both national and regional levels to ensure that only safe, effective and inexpensive drugs are marketed.2/

135. In the various studies conductged by the UNCTAD, the need for strengthening the institutional arrangements for quality control and testing of drugs in several countries has been highlighted.3/ to 8/

136. In view of this position, countries that do not have laws to regulate the import and manufacture of drugs may enact such laws. There are several model legislations available, which can be adopted with suitable modifications.

1/ Technology Policy in the pharmaceutical sector in developing countries - UNCTAD/TT/7 p.6

2/ Guidelines on technology issues in the pharmaceutical sector in the developing countries - UNCTAD/TT/49 p.15

3/ Technology policies in the pharmaceutical sector in the Phillipines UNCTAD/TT/36 p.27

4/ Technology policies in the pharmaceutical sector in Nepal - UNCTAD/TT/34 p.30

5/ Technology policies in the pharmaceutical sector in the United Republic of Tanzania - UNCTAD/TT/135 p.30

6/ Technology policies in the pharmaceutical sector in Venezuela UNCTAD/TT/25 p.28

7/ Report and recommendations of the workshop on trade and technology policies in the pharmaceutical sector in the Carribbean region - UNCTAD/TT/25 p.28

8/ Guidelines on technology issues in the pharmaceutical sector in the developing countries. UNCTAD/TT/49 Annex V p.5

Areas of Legislation

137. The priority areas requiring suitable legislation in countries where quality assurance of drugs is weak are listed below:

a. Setting up of a Drug Control Administration;

b. Selection of a list of essential drugs for the country;

c. Use of generic names whenever possible;

d. Registration of drugs limited to the list prepared and based on technical information from neighbouring countries, regional organisations or international agencies (eg. WHO);

e. Imports, local production and distribution limited to drugs registered in the country;

f. All imports to be channelled through a State purchasing agency so that quality assurance can be built into the purchasing procedure: the possibility of sub-standard drugs entering the market will therefore not arise;

g. Control of marketing practices such as advertising; information on and promotion of drugs;

h. Control of labelling of products and surveillance of marketed products;

i. Exchange of information among countries on pharmaceutical inspection;

j. Development of basic tests for the analysis of the most essential drugs;

k. Inspection of manufacturing establishments, stores and pharmacies;

l. Regulation of multi-source international procurement;

m. Legal definition of drug distribution system at the central, regional and peripheral levels.9/

138. If suitable legislation is enacted to implement the measures listed above, the drug control authority of a country could function optimally with minimum resources.10/

Drug Control Administration

139. The first priority, as mentioned above, under the legislation, should be the setting up of a strong independent Drug Control Administration, for

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9/ Guidelines on technology issues in the pharmaceutical sector in the developing countries - UNCTAD/TT/49 p.15/16

10/ Ibid. p.16

implementing the provisions of the law, and with clearly defined responsibilities for:

i. Establishing quality control standards and other regulatory measures relating to drugs;

ii. Quality control of marketed drugs;

iii. Registration of new drugs to verify their efficacy, safety, and necessity;

iv. Disseminating scientific information about pharmaceutical products to the medical profession; and

v. Drawing up a National Formulary and a National Pharmacopea.

140. In the initial stages, when drugs are imported, the administration should ensure that sub-standard and harmful products are not imported into the country, and where there is a domestic industry create confidence in the medical profession and consumers about the quality of the pharmaceuticals which it produces.

Drug Laboratory

141. One or more quality control laboratories for drug analysis, depending on the workolad and the size of the country should start to operate as soon as possible. Some of the smaller countries may consider setting up regional laboratories for drug analysis, while for more sophisticated analysis, such as bio-availability studies, samples can be referred to laboratories in more advanced countries or even to some academic institutions within the country which may have facilities to undertake the requisite tests. The overall responsibility for coordinating the analysis of marketed drugs, whether imported or domestically produced, would,of course, be that of the drug control administration.11/

Registration of Drugs

142. A key instrument in implementing national drug policies regarding generic names, essential drugs, costs and prices and the restriction of the number of formulations is the registration of new drugs which should be the responsibility of the drug control administration. Only those new drugs which, considering the balance of efficacy, safety and cost, have distinct advantages should be registered. Clear guidelines should be established regarding the information and data to be furnished for registering new drugs in addition to guidelines for the evaluation of clinical trials to be conducted as precondition for registration.12/

WHO Initiatives

143. Two notable initiatives were taken by the WHO in assuring the quality of drugs. One is the "Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce" launched in 1975. Under the scheme,

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11/ Technology policies and planning for the pharmaceutical sector in the developing countries - TD/B/C.6/56 p.11

12/ Technology policies and planning for the pharmaceutical sector in the developing countries - TD/B/C.6/56 p.11

certificates for specific products are issued by the competent authority of the exporting countries at the request of the importing countries. Such certification is of particular value when the manufacturer is unknown to the importing authority or when a drug is imported for the first time. So far 110 countries have agreed to participate in the scheme through designated national authorities. The objective of the scheme is to provide a simple administrative mechanism whereby importing countries can:

i. Obtain assurance that a given product has been authorised to be placed in the market in the exporting country, and, if applicable, obtain information on the reasons for a product not being authorised to be placed on the market in the country of export.

ii. Obtain assurance that (a) the manufacturing plant in which the product is produced is subject to inspection at suitable intervals and (b) conforms to requirements for good practices in the manufacture and quality control of drugs, as recommended by the World Health Organisation.

iii. Exchange information on the implementation of inspection and controls exercised by the authorities in the exporting country. In the case of serious quality defects in the importing or the exporting country, such information and requests for enquiries may also be exchanged.13/

144. The second is the WHO Code of "Good Practices in the Manufacture and Quality Control of Drugs (GMP)" which contains general guidelines for the adoption of good practices in the manufacture of pharmaceuticals. Both, the scheme and the code were adopted by the 28th World Health Assembly and recommended for adoption by Member-States of WHO.14/

13/ Certification scheme for the quality of pharmaceutical products moving in international commerce - WHO - September '85 - p.3

14/ Ibid. p.5

Chapter XII

MARKETING OF PHARMACEUTICALS

145. An aspect of the operations of the pharmaceutical industry which has drawn unfavourable comments, is the marketing (sales promotion) activity, specially of TNC's in developing countries.

Issues relating to Marketing Promotion

146. The promotional practices of pharmaceutical firms raise a number of issues relating to health care and pricing of drugs in developing countries. These issues are closely interrelated but they can be grouped into 4 categories; each represent distinct problem areas and may require different policy responses: (1) prices of pharmaceuticals, (2) national health policies and priorities, (3) domestic production capacity and (4) marketing of unsafe pharmaceuticals.1/

147. The high cost of promotion is reflected in the high price of branded drugs. Studies made by UN agencies have shown that branded drugs are generally priced higher than the same drugs sold under generic names and constituted a significant percentage of sales.2/

148. High-pressure promotion also motivates doctors to prescribe more expensive medicines even when lower-priced equivalents of comparable quality are available. One reason for their apparent insensitivity to price may be that the promotional techniques used by most firms aim at underplaying the price element. Instead, they focus on the various qualities, real and imaginery of the drug and what distinguishes it from otner similar drugs. As a result, physicians tend to base their selection on the products claimed qualities as described in promotional materials and less on their prices.3/ In developing countries with scarce resources and where the purchasing power of patients is low, the cost of drugs has to be carefully considered, because the choice may be not between high or low-cost treatment but between low-cost treatment or no treatment at all for some patients.

Product Differentiation; Brand Name Promotion/Advertising

149. The promotional strategy on 'product differentiation' takes variety of forms such as: (a) different brandnames for the same drug; (b) differing dosage forms; (c) different derivations of the same molecular structures; (d) combinations of existisng drugs; (e) different drugs with the same therapeutic

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1/ Transnational corporations in the pharmaceutical industry of developing countries - ST/CTC/49

2/ Ibid. p.24

3/ Ibid. p.22

effects. Probably the most common form of product differentiation in developing countries is the use of combinations of existing products. Product innovation is often motivated by the desire of the firm to increase or maintain sales and market share.4/

150. Product competition and promotion is closely linked to patents and brand names. While patents grant temporary monopoly power for the patent-holder, brand names combined with intense promotion enables firms to exercise market power in a particular therapeutic sub-market even after the patent has expired or when a patent is not effective. Patent combined with brand name confers on companies formidable market power. Brand name also result in prolil-feration of names for identical substances.5/

151. If promotion exerts a powerful influence in developed countries where doctors have ample alternative sources of information on pharmaceuticals, the impact in the developing countries where drug information is more scarce can be expected to be even greater. A study in Brazil concluded that the main sources of information of the medical profession are directly or indirectly linked to the promotional activities of private firms.6/

152. Marketing promotion may, interalia, be an contributory factor to the asymmetry that exists between drug consumption and requirements in most developing countries. In Thailand consumption of antibiotics was seven times the requirement for the drugs based on an analysis of morbidity patterns, while in other drugs dealing with specific priorities of the country there were signifi-cant under consumption (e.g. consumption of anti-TB drugs was only 5% of the estimated drug requirements).7/ As a result of this assymmetry, in some cases serious shortages of essential drugs cripple health care delivery systems while at the same time there is an overabundance of less necessary drugs, such as tonics, vitamins and cough syrups.8/

Policies for Regulating Marketing Practices

153. From the foregoing analysis, it is clear that the cost inherent in the present marketing of drugs arises from the emphasis on industrial property system of brand names and the expenses and confusion of marketing them. A rational marketing policy must, therefore, tackle this fundamental anamoly and aim at the marketing of good quality, reasonally-priced pharmaceuticals that meet real national medical need, reduce excessive product differentiation, heavy

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4/ Transnational Corporations in the pharmaceutical industry of develop-ing countries - ST/CTC/49 p.22

5/ Ibid - p.22

6/ Ibid - p.23

7/ Ibid - p.27

8/ Ibid -p.27

promotional expenditure, inaccurate and inconsistent promotional materials and unethical marketing techniques. To achieve this aim a broad range of policies can be used by the developing countries. The policies listed below may be effective:9/

1. The adoption and use of an essential drug list for both the public and private sector would be an important tool to rationalize drug policy and help to ensure the availability of drugs which respond to national health priorities and needs.

2. Setting up of an adequate system for correct information for drugs and their price to the doctors. This may not be difficult if the system provides for only a few hundred essential drugs. Health and medical training should provide future doctors and health workers with objective sources of information on pharmaceutical products, ensure familiarity with and use of generic names and encourage doctors and health workers to be familiar with the economic issues of drug prescribing, so that the quality and price of drugs become a major factor in decisions about appropriate treatment.

3. Careful revision should be made of the industrial property system. The replacement of brand names by generic or non-propriety names (such as those provided by the WHO) must be a basic part of the reform. However, the change should not be made suddently but in a phased manner based on advice of medical practitioners.10/ However, if trade marks are used, all pharmaceutical products should be required to display prominently the generic name along with the trade mark.

4. If brand names are retained, tighter controls can be imposed on their promotion. The expenses of marketing can be made subject to tax and the proportion of turnover devoted to advertising and free samples can be fixed by law.

5. Promotion of drug should be regulated. Promotional material and product information should receive pre-clearance from health authorities to ensure that information is balanced and accurate and that complete information on side effects, and warnings is disclosed. Expenditure on promotion could be limited as could, such practices as random and large scale distribution of samples, discounting, and expensive gifts to doctors, health workers and government officials.

6. The quality, safety and efficacy of drugs should be ensured through effective pre-marketing testing and registration and post-marketing surveillance, including a system of adverse drug reactions reporting.

9/ Transnational corporations in the pharmaceutical industry of developing countries. ST/CTC/49 p.62

10/ Ibid. p.62

7. Rules prohibiting the scale of prescription drugs over the counter without a prescription should be enforced.

8. International and regional action, in co-operation with the relevant international and regional organisations, should be taken to ensure adequate standards for marketing and promotion of pharmaceuticals, including the development of an international framework for pharmaceuticals.

Legislation - Voluntary Action

154. Experience has shown that legislation alone is not adequate to control and regulate marketing and promotion. It has to be supplemented by voluntary action by the industry and pressures from health professionals. The right mix of legislation and voluntary action would produce the desired results.

IFPMA Code

155. The industry and its associations in some developed countries have voluntarily adopted codes of marketing practices and have also set up machinery to monitor its implementation and to take action against companies violating the code (e.g. Code of Marketing Practices of the Associations of the British Pharmaceutical Industry (ABPI). At the international level, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), took the initiative to evolve voluntarily a 'Code of Marketing Practices' and has recommended it for adoption by all its member-associations and their member-companies. The IFPMA Code was the first recognition on the part of pharmaceutical manufacturers, internationally, of the need for establishing and promoting ethical principles and practices throughout the pharmaceutical industry. In its preamble, the IFPMA Code recognises the "pharmaceutical industry's international responsibilities" and states that manufacturers are prepared to "accept certain obligations in so far as their marketing practices are concerned". The Code contains provisions concerning obligations of industry, general principles, medical representatives, symposia, congresses and other means of verbal communication, printed promotional material and samples, and a supplementary statement.

Comments on the Code

156. The IFPMA Code was a first step in the right direction. It has led to considerable discussion in various forums, such as WHO, UNCTAD, the Group of 77, the Parliamentary Assembly of the Council of Europe and various non-governmental organisation, in particular the International Organisation of Consumers Unions (IOCU) and Health Action International (HAI). Two types of comments were voiced in these forums. First, the scope of the code was said to be far too narrow in that it dealt only with marketing practices and failed to touch on subjects of great importance to consumers, and particularly to developing countries, such as, drug registration, clinical trials and introduction of new drugs, drug information and promotional material, pricing and distribution, technology and production issues, research and development, utilisation and commercialisation of R & D results, etc. The second type of criticism followed from

the first; universally respected norms and standards for pharmaceuticals could evidently not be evolved by the manufactures alone, but would require the active participation of all the interests concerned, particularly the consumers and those responsible for formulating and implementing different elements of health and pharmaceutical policies.11/

Comments of HAI on IFPMA Code

157. The next step was the publication in 1982 by Health Action International (HAI), of "A Draft Proposal for an International Code on Pharmaceuticals; Discussion Document". The HAI draft code invited comments from experts and states that its adoption will require the expertise of various agencies, most importantly, WHO and UNCTAD. The HAI response to the IFPMA code was not confined to marketing practices alone; it covered all important matters having a very direct bearing upon the interests of the consumers, particularly in the developing countries. HAI pointed out that because the code makes no provisions for interpretation, monitoring and enforcement, its impact can be expected to be negligible.12/

158. Despite its shortcomings, the IFPMA code constitutes the first collective action by the industry to improve its marketing practices. According to WHO "it is a good beginning to raising ethical standards in drug production and marketing".13/ WHO has reportedly decided to follow up closely the implementation of IFPMA Code and restrain from pursuing vigorously for the promotion of its own code during a trial, but unspecified, period.

159. Developing countries may encourage pharmaceutical industries in their countries to voluntarily adopt a code of ethical marketing practices and actively involve representatives of health professionals and consumers in monitoring marketing practices of the industry on a continuing basis.

11/ Appropriate strategies for facilitating pharmaceutical supplies to developing countries - TD/B/982 p.9

12/ Transnational corporations in the pharmaceutical industry of developing countries - ST/CTC/49 p.38

13/ Address by Dr. H. Mahler, Director General, WHO, to the International Federation of Pharmaceutical Manufacturer's Associations, Washington D.C. (June'82).

Chapter XIII

SAFEGUARDS AGAINST MARKETING UNSAFE DRUGS

160. In recent years there has been a growing concern regarding the manufacture, marketing, distribution and use of certain pharmaceuticals that can produce severe and sometimes fatal adverse side effects, and the export to developing countries of products which have been banned or severely restricted in some developed countries.

Relevant Issues

161. The issues relating to the marketing of unsafe pharmaceutical can be divided into four types: (a) the marketing of pharmaceuticals that are unsafe because of pharmacological dangers inherent to the medicine itself: (b) the marketing of pharmaceuticals without complete information essential for their safe use: (c) the marketing of pharmaceuticals in an environment where lack of adequate medical technologies, personnel or financial resources renders the product unsafe; and (d) the marketing of pharmaceuticals where the social context prevents the proper use of the product.1/

162. The first type is concerned with drugs that are inherently unsafe. This would include certain poor quality pharmaceuticals due to impurities, contaminants or incorrectly formulated dosages, or unstable or fluctuating bioavailability. Poor quality is generally not a problem with the products of firms which normally observe good manufacturing practices.

163. A second category consists of those pharmaceuticals whose risks are so great that they outweigh the benefits derived from treatment, taking into account available alternatives. Many of these products are not registered or are banned or severely restricted in developed countries. In this context, it may be pointed out that there is no unanimity in the action taken by countries for withdrawal of drugs and whereas one drug may be withdrawn by one developed country, it could continue to be marketed in other developed countries. Thus, drugs which have been withdrawn in the USA are still marketed in the European countries and even within the European countries, there is no unanimity regarding the withdrawal of drugs.

164. A much larger group of pharmaceuticals are those drugs that may become unsafe if they are used incorrectly. Sometimes misuse of these drugs is attributable to incomplete or inadequate information about the indications, counterindications, warnings and side effects provided to health authorities, doctors, pharmacists and patients during registration and marketing.

1/ Transnational corporations in the pharmaceutical industry of developing countries - ST/CTC/49 p.31

165. In view of the widespread feeling that people in the developing countries may be unnecessarily exposed to health risks arising from marketing harmful drugs, measures have been contemplated in developing countries to provide legal safeguards against marketing of harmful drugs. Also, as a result of the adverse media publicity given in this regard by voluntary organisations concerned with health care, manufacturers in developed countries also are phasing out manufacture of some of the most harmful drugs.

Role of WHO

166. The WHO periodically circulates to its member-countries information about regulatory action in developed countries to restrict, prohibit, or modify the marketing of specific drugs in the light of new knowledge about their therapeutic usefulness or side-effects. Although countries like India make use of such information to make appropriate changes in their own regulatory rules, most developing countries are unable to do so because the administrative/legal machinery for suitable action does not exist or is grossly inadequate.

167. It is not suggested that no developing country should permit marketing of drugs not approved or banned in the countries of origin. What needs to be emphasised is that it should be the basic legal and moral responsibility of the supplier to disclose full information about the hazards of the products supplied not only initially but on a continuing basis and as long as the products are marketed and leave it to the judgement of the recipient countries to take a final decision as to whether to prohibit or permit continued marketing.

Full Disclosure of Information

168. Full disclosure of information about harmful effects thus should be made mandatory on the supplier who should certify or guarantee that the drug is marketed in the developing countries for the same indications as in the countries of origin and that the literature distributed along with it giving side-effects and contra-indications are identical to those given to medical practitioners in the developed countries. The background paper on preparation of guidelines for transfer of pharmaceutical technology prepared for the UNIDO. First Consultation Meeting held in Lisbon in December 1980 puts this issue in perspective as follows:-

> "The supplier's duty to inform, completely and correctly, about the properties and effects of products involved in a licensing agreement, should not be confined to the negotiating phase, but be envisaged on a continuous basis for the lifetime of the agreement. New research, stringent controls or prolonged application of a drug may reveal effects which were unknown at the time of signing of the agreement. More restrictive requirements in certain countries may also imply the prohibition of certain drugs or therapeutical uses. It will be a basic ethical and legal duty of the supplier to bring all these events, without delay, to the knowledge of the recipient."2/

2/ First Consultation Meeting on Pharmaceutical Industry Preparation of guidelines - background paper ID/WG-331/3 p.30

Institution for Monitoring Drug Reaction

169. Most developed countries have elaborate mechanisms for monitoring adverse drug reactions and action to withdraw drugs is, therefore, initiated by them. In many developing countries, there is mechanism at the national level for an effective drug reaction monitoring. It may be useful to make a beginning by building up the data on this in selected Government and private hospitals.

Chapter XIV

TRAINING OF TECHNICAL PERSONNEL

170. Pharmaceutical production calls for a wide range of experience and expertise to set up and operate commercial scale manufacturing enterprises. Top priority should be given for the creation of facilities for the training of appropriate personnel such as pharmacists, quality control personnel, pharmaceutical and chemical technologists, biotechnologists and management experts. While some developing countries already have training facilities for appropriate technical personnel in the categories mentioned above, others do not have such facilities or the training facilities available are inadequate.

171. The UN agencies in the various country studies conducted by them have assessed the situation so far as availability of training facilities for pharmaceutical technicians is concerned and highlighted the need for strengthening the training arrangements and establishing training institutions in the countries in Africa, Caribbean Region and Asia.1/ to 4/

172. In Cuba, production personnel are trained by the industry itself under programmes approved by the Ministry of Education. The industry cooperates with educational institutions in structuring the curriculum for the professional cadres needed and allows students to receive practical training. In India, most of the universities offer courses in chemical engineering and chemical technology in addition to Government-run institutes of technology. There are 148 pharmacy colleges with an outturn of 7,000 pharmacy graduates per year, 50% of whom are absorbed in the pharmaceutical industry.

Role of UNIDO in Training of Pharmaceutical Personnel

173. Recognising the importance of the availability of trained personnel for establishing and operating pharmaceutical plants in developing countries, UNIDO has played a key role in organising training facilities under its technical assistance programmes. In general, the training imported falls into three cate-

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1/ Report and recommendations of the workshop on trade and technology policies in the pharmaceutical sector (Abidjan, Ivory Coast) UNCTAD/TT/48 p.20.

2/ Technology and development perspectives of the pharmaceutical sector in Ethiopia UNCTAD/TT/58 p.41.

3/ Report & recommendations of the workshop on trade and technology policies in the pharmaceutical sector in the pharmaceutical sector in the Caribbean Region UNCTAD/TT/41 Rev. 1 p.5

4/ Technology policies in the pharmaceutical sector in Nepal - UNCTAD/TT/34 p.24

gories, namely:

a. Training organised in cooperation with the government of a specific country eg. Belgium, France and Romania.

b. Training in the form of workshops, seminars and group programmes in collaboration with the government or industry. They cover certain specified field, are more intensive and comprise theory as well as practice.

c. Training as an element of technical assistance project. Under this category, the training is organised for personnel who are working in a pharmaceutical project during implementation as well as on completion. The training may be organised either by UNIDO directly or it is made a part of a contract for the establishment of a specific pharmaceutical project. Facilities for training in pharmaceutical units are provided by both developed and developing countries.

Cooperation in Training

174. The steps to be taken for setting up training facilities and the development of technical manpower resources will vary to some extent from country to country. However, each country should estimate its requirements of trained manpower to match its phased manufacturing programme and draw up an appropriate training programme.5/ There is considerable scope for cooperation among developing countries themselves in the field. Training obtained in another developing country will be more relevant and appropriate to the scientific and technical environment in which the persons trained will have to operate than training in a developed country.6/

Forms of Training

175. Cooperation could take the form of (1) short visits of experts from countries with more developed drug industry to assist and guide in setting up and running the new manufacturing units and for training manpower; (2) tours by students and apprentices to other developing countries to study for academic degrees or to receive on the job training and instruction in specific operations.7/ Existing organisations such as Cooperative Production and Training Centre (COPPTEC) could play an effective role in creating regional and inter-regional facilities for training. Organising training at regional level in drug procurement, quality control and stores management is one of the functions of the Caribbean Centre for Pharmaceuticals approved by the 4th Conference of Ministers Respon - sible for Health in the Caribbean held in July 1978.

5/ Technology policies and planning for the pharmaceutical sector in the developing countries - TD/B/C.5/56 p.28

6/ Ibid. p.28

7/ ibid p.28

177. Some initiatives have been taken by the WHO in collaboration with IFPMA in this regard. The IFPMA has already arranged for training quality control personnel in some of the developed and developing countries such as India. Under this scheme the WHO meets the expenses of travel of the selected candidates to the country of training and the local expenses are met by the companies who offer training facilities. The number of candidates to benefit from the WHO-IFPMA training scheme is 49, of which 37 have completed training and 12 are either undergoing training or waiting to take up training posts offered to them.8/

8/ IFPMA Bulletin, December, 1985, p.12

Chapter XV

LEGAL FRAMEWORK/ADMINISTRATIVE MACHINERY FOR IMPLEMENTING INDUSTRIAL DRUG POLICY

177. The various elements of an industrial drug policy dealt with in the foregoing chapters, require for effective implementation, a proper legal framework and administrative machinery for the control and regulation of the pharmaceutical industry.

Drug Legislation and Administrative Ministries/Departments

178. The legislation may fall into two broad categories:

1. Those relating to control over the quality, safety and standards of all drugs imported into and/or manufactured and marketed in the country.

2. Those relating to other aspects of manufacture and marketing of drugs, such as investment, foreign collaboration, licensing of production facilities, import of capital equipment, technology and raw materials, pricing, patents and trademarks.

179. In a Federal set-up, it is possible that both the Federal Government, and the State Governments, may enact legislation in respect of matters referred to above.

180. As an illustration, the main areas of control and regulation falling within the jurisdiction of the various Ministries of the Central Government in India may be mentioned.

	Ministry (Central)	Areas of Control/Regulation
1.	Ministry of Health	Health registration/new drugs/clinical trials/quality and standards of existing and new drugs/enforcement of the Drugs Act & Rules.
2.	Ministry of Industry, Department of Chemicals and Petro-chemicals (administrative ministry responsible for overall control, regulation and growth of the pharmaceutical industry)	Implementation of the drug policy/ fixation of prices of bulk drugs and formulations/allocation of production capacities to different sectors/licensing of new units and expansion of existing ones/policy regarding allocation of canalised (imported) raw materials/ categorisation of technology into "high" and "low".

3.	Ministry of Industry, (Department of Industrial Development)	Location policy/licensing/implementation of IDR Act/Bureau of Industrial Costs and Prices (BICP) which undertake cost studies for the purpose of price fixation/trade marks (brand name)/patents.
4.	Ministry of Commerce	Import-Export trade control/import licenses/import of capital equipment and canalised raw materials.
5.	Ministry of Finance	Foreign investment policies/implementation of Foreign Exchange Regulation Act (FERA)/remittance abroad. (dividend, royalty, technical service fee, etc.)/customs/excise duties/corporate taxation/control over capital issues/ credit.
6.	Ministry of Labour	Labour legislation/bonus.
7.	Ministry of Law	Company law/enforcement of MRTP Act.

Development Council at the National Level

181. It may be useful, as has been done in India, to set up a National Council for Drugs and Pharmaceuticals, consisting of representatives of Government producers, consumers, medical profession and technical experts, to advise the Government from time to time, on various matters relating to the production of drugs, utilisation of installed capacity, norms of efficiency, administration of the pricing scheme, marketing arrangements, induction of technology etc.

Regional & International Cooperation

182. At the regional/sub-regional levels, developing countries should promote cooperation among themselves in the pharmaceutical sector in evolving and implementing technology policies, including establishment of regional pharmaceutical centres for procurement and production. The countries of CARICOM, ASEAN and CEAO have taken important initiatives in this regard.

183. At the international level, on the basis of the pooled experience of developing countries and the lessons distilled therefrom, new norms and standards should be evolved for improving developing countries' access to pharmaceutical technology and then move further on to an international effort under the aegis of WHO, UNCTAD, UNIDO and other United Nations agencies to evolve special norms and standards for the pharmaceutical sector covering marketing, trade, distribution, access to technology and promotion of development of national technology.

Chapter XVI

REGIONAL AND SUB-REGIONAL COOPERATION

Scope for Cooperation

184. The development of the pharmaceutical sector in a country requires simultaenous action on many fronts. Such action has to originate from efforts at the national level. The resources available in many of the developing countries however, are not sufficient for the purpose. Moreover, many developing countries are too small to achieve the economy of scale that is critical to the operations of certain parts of the pharmaceutical supply system or to reach the necessary volume of purchase for an efficient centralized procurement system. The pharmaceutical industry is one of the sectors which offers the best prospects for co-operation among developing countries. Co-operative action could cover many areas from joint purchase, distribution and production of pharmaceuticals to research and development efforts directed to the specific disease pattern and particular conditions of developing countries.1/

185. So far as inter country pooled procurement schemes are concerned, several concrete initiatives have already been taken. But co-operation needs to go beyond procurement of drugs. In view of the technological complexity and the economies of scale in manufacture of the basic chemicals, as well as the size of the capital requirements, it is unlikely that many developing countries can achieve self-reliant pharmaceutical production and technology on their own. However, several developing countries have moved to supplement their own efforts to rationalise pharmaceutical policies by establishing regional or sub-regional arrangements. This issue has therefore, progressed from exploration to preparation of concrete arrangements and blue-prints for sub-regional cooperation and actual implementation in some cases.2/ The UNCTAD studies have also highlighted the need for some countries to examine the scope for possible areas of cooperation with other countries and the UNCTAD advisory service on technology has also carried out a number of missions to advise on

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1/ Technology policy and planning for the pharmaceutical sector in developing countries, TD/B/C.6/56 p.29-31

2/ Transnational Corporations in the pharmaceutical industry of developing countries - ST/CTC/49 p.58

the formulation of national and regional pharmaceutical policies; for example, Tanzania, Nepal, Philippines, Cuba, Andean Group. 3/ to 6/

Regional Cooperative Production and Technology Centres

186. It was against this background that the idea of Regional Cooperative Production and Technology Centre (COPPTECs), gained universal acceptance. The economic resolution adopted by the Sixth Conference of Heads of State or Government of Non-Aligned Countries, held in Havana, Cuba (1979), endorsed the recommendation made by the inter-Secretariat task force, for the establishment, within two years, of three to six COPPTECs.7/

Functions of the Caribbean Centre

187. The Fourth meeting of the Conference of Ministers responsible for Health in the Caribbean recommended the establishment of a Caribbean Centre for Pharmaceuticals with the following functions:

a. Operating an expanded regional pooled procurement system for drugs;

b. Promoting industrial co-operation among the countries in the region engaged in pharmaceutical production;

c. Compiling a Caribbean Formulary;

d. Disseminating production information through regional publications;

e. Assisting countries in setting up at the national level of pooled procurement systems, inventory controls, etc.

f. Assisting countries in revising their patent legislation in the area of pharmaceuticals;

g. Assisting local producers of pharmaceuticals in obtaining equipment, technology and other inputs under the best terms and conditions;

3/ Technology policies in the pharmaceutical sector in the United Republic of Tanzania - UNCTAD/TT/35 p.32

4/ Technology policies in the pharmaceutical sector in Nepal UNCTAD/TT/34 p.32

5/ Technology policies in the pharmaceutical sector in the Philippines UNCTAD/TT/36 p.27

6/ Technology policies in the pharmaceutical sector in Cuba UNCTAD/TT/33 p.49

7/ Guidelines on technology issue in the pharmaceutical sector in the developing countries - UNCTAD/TT/49 Annex VI p.52

h. Organising training at the regional level in international drug procurement, quality control, stores management, etc;

i. Exploring possibilities of co-operation with other countries and regional organisations, for example with regard to market information, trade, industrial co-operation, co-operation in the field of transfer of technology;

j. Providing a forum for discussion for regional pharmaceutical producers in order to facilitate the rationalization of production.8/

Other Sub-Regional Schemes of Cooperation

188. Another area which also lends itself to regional or sub-regional cooperation is the production of basic chemicals needed for setting up drug formulation units. Even if the countries cooperating in this area are geographically widely spread, the main inputs besides those of the chemical and related industries, are those of skilled manpower which could be easily transferred from one country to another. Thus, it would be quite feasible for Argentina to cooperate with Kenya or India with Peru in a cooperative expansion of pharmaceutical facilities with the more highly industrialised countries concentrating on the production of the more complex chemicals and the less industrialised countries engaging in drug formulation. Since the primary input for the manufacture of synthetic drugs is petrochemicals and since many petrochemicals industries are being established in oil producing developing countries, it is clear that the oil producing countries could be a major partner in a COPPTEC scheme.9/

189. Other examples of subregional grouping of developing countries with a view to co-operation in the pharmaceutical sector include the following:10/

1. The South Pacific island nations have their common market which takes the form of the South Pacific Bureau for Economic Cooperation (SPEC). Health officials of these countries have agreed to establish a collective drug purchasing scheme with the assistance of WHO and co-operation from UNCTAD.

2. The establishment of a pharmaceutical centre has been proposed for the countries of the CEAO (West African Economic Community). This initiative is being followed up by UNCTAD and the Council of Ministers of the CEAO has decided to create a Technical Committee on Drugs and Pharmaceuticals, with the object of studying, in co-operation with UNCTAD, practical means of implementing the measures recommended by a CEAO committee of experts on the subject.

8/ Technology policies and planning for the pharmaceutical sector in the developing countries - TD/B/C.6/56 p.30

9/ Major issues in the transfer of technology to developing countries TD/B/C.6/4 p.62

10/ Ibid p.62

3. The Commonwealth Regional Secretariat for the East, Central and Southern Africa region, based at Arusha, United Republic of Tanzania, is setting up a scheme for the joint purchase of drugs in the African countries which it serves, namely Botswana, Kenya, Lesotho, Malawi, Mauritius, Seychelles, Swaziland, Uganda, United Republic of Tanzania, Zambia and Zimbabwe. 11/

4. The Five ASEAN countries (Indonesia, Malaysia, Philippines, singapore and Thailand) have taken initiatives in promoting subregional co-operation in the sector.

5. The countries of the Andean group had initiated studies (1983) for establishing a centralised purchasing unit for pharmaceutical chemicals. 12/

190. A new and welcome development is the cooperation among countries of the South Asia (India, Pakistan, Bhutan, Nepal, Bangla Desh, Shri Lanka and Maldives) in special areas of work which has been endorsed in the meeting of the Heads of States of these countries held in Dhaka in November 1985. Since there is a scope in this region for cooperation in the pharmaceutical sector, it is hoped that attention will be given to this aspect after the Secretariat of the South Asian Association for Regional Cooperation is located and starts functioning.

11/ Technology policies & planning for the pharmaceutical sector in developing countries-TD/B/C.6/56 - p.30

12/ Transnational Corporations in the pharmaceutical industry of developing countries - ST/CTC/49.p.59

Chapter XVII

RESPONSIBILITIES OF VARIOUS PARTIES

191. In conclusion, the major responsibility of the various parties involved in the formulation and implementation of a national industrial drug policy as it evolves from readings of all the aforementioned elements extracted from UN studies on the subject may be defined among others as follows.

Responsibility of UNIDO

(a) To assist the developing countries in formulating industrial drug policies.

(b) Provide technical assistance to developing countries for development, expansion and rehabilitation of the pharmaceutical industry by arranging for transfer of appropriate technology in the areas of production, management, design and technology from formulation and packaging of drugs to more sophisticated chemical process drugs; valorisation and utilisation of medicinal plants in the interest of the local pharmaceutical industry, supply of machinery and equipment.

(c) Organise consultations, seminars, expert group meetings to identify policy issues relating to the development of pharmaceutical industry, with a view to finding solutions through (i) cooperation between developed and developing countries, (ii) among developing countries and (iii) international cooperation.

(d) Organise training programmes for technical personnel in different disciplines in pharmaceutical plants, laboratories and universities.

Responsibility of Government

- To formulate and implement an industrial drug policy within the framework of national drug policy keeping in view the resources, raw-materials, infrastructure and trained manpower available in the country.

- To enact legislation and establish the administrative machinery for implementation of the various components of the drug policy.

- To prepare a list of essential drugs to be produced indigenously.

- Institutionalise arrangements for centralised purchases of finished products, raw materials, intermediates and bulk drugs on competitive tenders.

- To formulate policy measures for the establishment, development, expansion of the drug industry in both public and private sectors.

- To provide both incentives and tariff protection to the industry.

- To promote the use of generics.

- To enact legislation to regulate foreign investment in the pharmaceutical sector including provisions relating to the transfer of the necessary technology under reasonable conditions.

- To ensure that regulatory authorities have adequate means to control the use of pharmaceuticals including marketing of harmful drugs.

- To strive for the lowest possible cost of pharmaceuticals and adequate quality standards.

- To enact legislation for ethical norms for advertising and promotion of pharmaceuticals.

- To formulate within the parameters of the drug policy, a pricing scheme which on the one hand, is flexible and can be administered with ease and on the other, provide for a reasonable financial return to the producers on their investment.

- To ensure that objective information about drugs is available to health care professionals.

Responsibility of the Pharmaceutical Industry

- To provide complete and objective information about marketed drugs.

- To adhere to good manufacturing practices.

- To comply with ethical norms for advertising and promotion.

- To develop new drugs for tropical diseases endemic in developing countries.

Responsibility of Medical Practitioners

- To follow rational medical prescribing practices

Responsibility of Consumer Representatives

- To improve the information on drugs that is relevant to the public.
- To monitor with vigilance full compliance with norms on advertising and promotion.
- To support essential drugs programme.

ANNEX I

List of Publications of UNIDO, UNCTAD, UNCTC, WHO, WORLD BANK concerned with factors having a bearing on industrial drug policies

UNIDO

1.	ID/WG/267/3	- The steps involved in establishing a pharmaceutical industry in developing countries. (1978)
2.	UNIDO/IOD.207	- Note on UNIDO activities relating to pharmaceutical products in the context of primary health programmes. (1978)
3.	ID/WG.331/5	- Availability, terms and conditions for the transfer of technology for the manufacture of essential drugs. (1980)
4.	ID/WG.331/6 & Add I	- Global study of the Pharmaceutical Industry - (1980)
5.	ID/WG.331/Rev I	- Report of the First Consultation on the Pharmaceutical Industry. (1980)
6.	ID/WG.331/8	- Illustrative List of drugs prepared by UNIDO in consultation with WHO. (1980)
7.	ID/232/10	- Appropriate industrial technology for drugs and pharmaceuticals. (1980)
8.	ID/WG.331/6/Add.I	- Technical cooperation among developing countries in the field of pharmaceutical industry. (1980)
9.	.....	- UNIDO for Industrialisation - Pharmaceuticals. (1980)
10.	UNIDO/PC.33	- Round Table meeting on the development of the pharmaceutical industry. (1982) (Mohamadia, Morocco)
11.	UNIDO/10.505	- Medicinals and Aromatic Plants for Industrial Development. (1982)
12.	UNIDO/PC/76	- Meeting on cooperation among developing countries (Tunis, Tunisia). (1983)

13. ID/WG.393/9 - Report of the Second Consultation on the Pharmaceutical Industry. (1983)

14. ID/WG/393.15 - The need for drug policies. (1983)

15. UNIDO/10.570 - UNIDO experience in implementing pharmaceutical projects in developing countries. (1984)

16. UNIDO/ID/WG.393/2/Rev1 - Directory of sources of supply of Pharmaceutical Chemicals, their Intermediates and some Raw Materials included in the UNIDO list. (1984)

17. ID/WG.393/1/Rev 2 - Items which could be included in contractual arrangements for the transfer of technology for the manufacture of those drugs (or intermediates) included in UNIDO's illustrative list. (1985)

18. ID/WG.393/4/Rev 2 - Items which could be included in contractual arrangements for the setting up of a plant for the production of bulk drugs (or intermediates) included in UNIDO illustrative list. (1985)

19. ID/WG.393/3/Rev 2 - Items which could be included in the licensing arrangements for the transfer of technology for the formulation of pharmaceutical dosage forms. (1985)

UNCTAD

20. TD/B/C.6/4 - Major issues in transfer of technology to developing countries. A case study of the pharmaceutical industry prepared by Dr. S. Lal in coordination with the UNCTAD secretariat. (1975)

21. UNCTAD/TT/7 - Technology policy in the pharmaceutical sector in developing countries. Paper prepared by UNCTAD secretariat (WHO consultation on drug policies). (1976)

22. APEC-TT/UNCTAD/CARICOM - Towards a regional pharmaceutical policy. Report of a joint mission to the Caribbean Region. (1977)

23. UNDP Project INT/009/A/01/99 - Pharmaceuticals in the developing world: policies on drugs, trade and production on inter-agency task force on pharmaceuticals. (1979)

24. TD/B/C 6.21 - Case studies in transfer of technology: pharmaceutical policies in Sri Lanka. (1977)

25. UNCTAD/TT/35 - Technology Policies in the pharmaceutical sector in the United Republic of Tanzania. (1980) AEFS

26. UNCTAD/TT/36 - Technology policies in the pharmaceutical sector in the Philippines. (1980) AEFS

27. TD/B/C.6/56 - Technology policies in the pharmaceutical sector in the developing countries. (1980)

28. UNCTAD/TT/33 - Technology policies in the pharmaceutical sector in Cuba. (1980) AEFS

29. UNCTAD/TT/41 - Report of the workshop on trade and technology policies in the pharmaceutical sector in the Caribbean Region. (1980) AEFS

30. UNCTAD/TT/34 - Technology policies in the pharmaceutical sector in Nepal. (1980)

31. TD/B/C.6/AC/5/4 - Trade marks and generic names of pharmaceuticals and consumer protection (1981) AEFS

32. TD/B/B.6/AC.5/4 - Examination of the economic, commercial and development aspects of industry property in the transfer of technology to developing countries. (1981)

33. UNCTAD/TT/48 - Report and recommendations of the workshop on trade and technology policies in the pharmaceutical sector. (1982) AEFS

34. UNCTAD/TT/25 - Technological policies in the pharmaceutical sector in Venezuela. (1982) AEFS

35. UNCTAD/TT/37 - Technology policies in the pharmaceutical sector in Costa Rica. Study prepared by Mr. Juan Carlos del. Bello in co-operation with the UNCTAD secretariat. (1982) AEFS

36. UNCTAD/TT/49 - Guidelines on technology issues in the pharmaceutical sector in developing countries. (1982)

37. TD/B/982 & Corr. 1 & Corr. 2 - Appropriate strategies for facilitating pharmaceutical supplies to developing countries. Note by the UNCTAD secretariat. (1984) ACEFRS

38. UNCTAD/TT/58 - Technology and development perspectives of the pharmaceutical sector in Ethiopia Prepared jointly by the UNCTAD Secretariat and the Ethiopian Centre for Technology. (1984) AEFS

UNCTC

39. ST/CTC/49 - Transnational corporations in the pharmaceutical industry of developing countries (UNCTC) 1984

WHO

40. WHO Technical Report series 722 - The use of essential drugs. (1985)

41. ..... - Certification scheme for the quality of pharmaceutical products moving in international commerce. (1985)

WORLD BANK

42. ..... - Health Sector Policy Paper. (1980)

ANNEX II

ILLUSTRATIVE LIST OF ESSENTIAL BULK DRUGS IDENTIFIED BY UNIDO IN CONSULTATION WITH WHO FOR PRODUCTION FROM BASIC OR INTERMEDIATE STAGE IN DEVELOPING COUNTRIES

A. **ANALGESICS**

1. Acetylsalicyclic 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.

ANNEX III

ILLUSTRATIVE LIST OF 9 ESSENTIAL DRUGS FOR WHICH FACILITIES FOR THE LOCAL MANUFACTURE OF ACTIVE INGREDIENTS SHOULD BE ESTABLISHED IN DEVELOPING COUNTRIES AND WHICH SHOULD BE GIVEN TOP PRIORITY

ANAGELSICS

1. Acetylsalicylic Acid

ANTI-INFECTIVE DRUGS

Antibacterial drugs

2. Ampicillin
3. Sulphadimidine
4. Tetracycline

Antifilarial drugs

5. Diethylcarbamazine

Antileprosy drugs

6. Dapsone

Antimalarial drugs

7. Chloroquine

Antituberculosis drugs

8. Ethambutol
9. Isoniazid

FEZER S.A. INDÚSTRIA MECÂNICA

Address: Estrada Rio Bugre, Km 01
89500 - Caçador - SC.
Brazil

Telex: (493) 397 FEIM BR

Telephone: (0496) 62-0273

Contact: C.A. Fernando Fezer

Field of activity

Equipment for veneering of wood and manufacture of plywood and wooden shapes.

Equipment for production of mechanical wood pulp.

Experience in developing areas/countries

- Equipments exported to Argentina and Chile.
- A number of equipments supplied to plywood and other industries in the Amazon Region, Brazil.
- Minimum recommended capacity for a plywood plant is in the order of magnitude of 300 to 400 square meters per month. For such capacity, investments would be in the range of US$ 600,000 to / US$ 700,000, ex-works.
- If good quality wood is available, this will be used for the external part of the plywood, thus obtaining a better product. Otherwise, using only ordinary wood, a popular product will be obtained.
- Labor for the above mentioned capacity will be 6 skilled workers and about 30 to 40 semi or non-skilled workers. An experienced manager and some clerks will fulfill plant labor needs.

Cooperation offered

- Company can send technician abroad for preliminary evaluation, provided expenses are paid by interested parties.
- Receives foreign representatives for technical visits but does not cover their travel expenses.

INVICTA MÁQUINAS PARA MADEIRA LTDA.

Address: Av. Major José Levy Sobrinho, 2500
13480 - Limeira - SP.
Brazil

Telex: (19) 1107 INMD BR

Telephone: (0194) 41-1500

Contact: Jair de Sampaio Barros

Field of activity

Machinery for wood processing: carpentries and cabinet-making (band saws, shapers, tenoning machines, circular saws, squaring circular saws, straightening machines, drilling machines, band sanders, / roughing planers, planers, wood lathes, etc).

Experience in developing areas/countries

- Machinery exported to almost Latin American countries and to / Nigeria.
- A number of machineries supplied to developing areas within Brazil.

Cooperation offered

- In principle can send technician abroad for preliminary evaluations at its own expenses.
- Receives visitors and trainees without covering cost of stay.

METALÚRGICA SCHIFFER S.A.

Address: Av. Ernesto Vilela, 1701
84100 - Ponta Grossa - PR.
Brazil

Telex: (422) 157

Telephone: (0422) 24-5644

Contact: Roberto Schiffer

Field of activity

Complete line of machinery and equipment for sawmills.

Experience in developing areas/countries

- Company has sold machines to all countries in Latin America.
- For logs of small diameter, the basic unit with an average capacity of two cubic meters per hour of planks, would require about US$ 12,000 for machinery.
- Till the moment about 3,300 units have been fabricated and supplied to clients.

Cooperation offered

- Can send technician abroad for preliminary evaluation and/or preliminary projects, subject to payment of international travel expenses.
- Receives visitors, without covering their expenses.
- Provides training courses without covering their expenses.
- Provides labor training and technical assistance for machinery supplied.

COMACC - MÁQUINAS PARA COUROS E CALÇADOS LTDA.

Address: Rua Julio de Castilhos, 351
93.300 - Novo Hamburgo - RS.
Brazil

Telex: (51) 5093 IDER BR

Telephone: (0512) 93-2038

Contact: Ivo Mayer Milbrath

Field of activity

- Machinery for leather processing and footware manufacture.
- Turnkey projects for footware manufacture plants.

Experience in developing areas/countries

- Factory for Argentina: 5,000 pairs of "mocassin" per day.
- Factory for Colombia: 2,000 pairs of "mocassin" per day.
- Factory of woman footware for the Northeastern region of Brazil. Capacity: 4,000 pairs per day.
- A factory to produce 1,000 pairs per day (8 hours) of man footware would require an investment of about US$ 450,000.

Cooperation offered

- Receives visitors and trainees not covering their expenses.
- Develops projects for specific client's needs.
- Provides labor training and technical assistance for machinery supplied.

INDÚSTRIA DE MÁQUINAS ENKO LTDA.

Address: Av. Pedro Adams Filho, 795
93.320 - Novo Hamburgo - RS.
Brazil

Telex: (051) 1369

Telephone: (0512) 95-3566

Contact: Ruy R. Engelmann

Field of operation

Complete machinery line for "Tannery Plants" (leather processing).

Experience in developing areas/countries

- Machinery exported for Peru, Colombia, Ecuador, Venezuela, Uruguay, Paraguay, Bolivia, Mozambique.
- Minimum tannery plant capacity: 100 leathers/day cowhide. Approximate investment (only equipment): US$ 130,000.

Cooperation offered

- The company can send a technician abroad for preliminary evaluations, subject to payment of travel costs.
- Receives visitors not covering their expenses.
- Subject to prior inquiry can receive trainees.
- Develops projects for complete tannery plants, on client's specific needs.
- Provides training of labor and technical assistance for machinery supplied.

L.P. COPÉ & CIA. LTDA.

Address: Rua Major Luiz Bender, 1
93300 - Novo Hamburgo - RS.
Brazil

Telex: (051) 1742 LPCO BR

Telephone: (0512) 93-1077

Contact: Luiz Frohlich or Carmen Helena Kauer

Field activity

Machinery and equipment for rubber industries (technical parts), leather (finishing units) and plastics (finishing units).

Experience in developing areas/countries

- Machinery and equipment exported to Argentina and Mexico.
- A number of machinery supplied to clients located in developing regions within Brazil.

Cooperation offered

- In principle and for clients account, company can send technician abroad for preliminary evaluation.
- Receives clients representatives for technical and commercial visits.
- Receives trainees, without taking responsibility for their expenses.

INDUSTRIA E COMERCIO MOTOTEST LTDA.

Address: Rua Madre Emilie Villeneuve, 265
04367 - São Paulo - SP.
Brazil

Telephone: (011) 246-0388 - (011) 522-6453

Contact: Guido Wunderlich

Field of activity

Machines for internal combustion engine boring (recuperation).

Experience in developing areas/countries

One machine exported to Bolivia.

Cooperation offered

The company, which is a relatively small outfit, can provide limi - ted assistence subject to prior inquiry.

INDÚSTRIAS JOÃO MAGGION S.A.

Address: Rua José Campanella, 501
07000 - Guarulhos - SP.
Brazil

Telex: (11) 39384

Telephone: (011) 209-8266

Contact: José Maria Melendez Aguero

Field of activity

- Machines for re-treading tires
- Machines for manufacturing tires and inner-tubes for motorcycles and agricultural and industrial vehicles

Experience in developing areas/countries

- Units have been exported to Uruguay, Paraguay, Chile and Argentina
- Machines supplied to developing regions within Brazil
- One machine with capacity for re-treading up to sixty tires per month, using the conventional system, would cost approximately US$ 25,000

Cooperation offered

- Analysis of raw materials
- In principle, and subject to prior analysis, the company can assign a technician abroad for preliminary evalutions, at its own expenses
- Receives visitors without covering their expenses
- Can develop projects for specific client's needs
- Provides training of labor and technical assistance for machinery supplied

NORDEQ - EQUIPAMENTOS INDUSTRIAIS DO NORDESTE S.A.

Address: Via Centro nº 4364
43700 - Simões Filho - BA.
Brazil

Telex: (71) 1426

Telephone: (071) 594-9051 - (071) 594-8611

Contact: Jurandy Ferreira Alves

Field of activity

- Plate working industry; metalic structures.

Cooperation offered

NORDEQ is a company located in the Northeastern Area of Brazil (developing region) and can offer the following assistance:

- design of plate working shops
- work shop organization assistance
- can receive trainees in supervising and managing of work shops. Travel expenses at client's account.

SCHMUZIGER INDUSTRIA E COMERCIO DE MAQUINAS LTDA.

Address: Alameda dos Arapanés, 310
08170 - São Paulo - SP.
Brazil

Telex: (11) 24353 INDM BR

Telephone: (011) 241-6642 - (011) 533-6821

Contact: Hans Werner Schmuziger

Field of activity

Complete plants for producing polyurethane foam mattresses.

Experience in developing areas/countries

- Paraguay: plant with a daily capacity of 100 mattresses, 400 / pillows and 400 furniture cushions. Approximate cost of machinery: US$ 40,000
- Bolivia: 3 plants supplied
- Colombia: plant with a daily capacity of 50 mattresses and 200 / pillows. Approximate cost of machinery: US$ 25,000
- Chile: plant for a 50 mattresses per day capacity. Approximate / cost of machinery: US$ 22,000
- Belize: plant for a 70 mattresses per day capacity. Approximate / cost of machinery: US$ 32,000
- Zaire: plant for 100 mattresses per day capacity. Approximate cost of machinery: US$ 36,000

Cooperation offered

- Company can send technician abroad to evaluate opportunities, / with cost of air travel for account of client.
- Company receives clients representatives for technical visits, / without covering their expenses.
- Company is also prepared to receive trainees, without supporting costs of their stay.
- In certain cases company is prepared to consider establishment of joint ventures.

SUBJECT INDEX (*)

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  (05), (09), (16), (17), (19), (38)

- Energy, conservation
  (04), (05), (08), (13), (15), (73)

- Fertilizers
  (08), (13), (39), (46)

- Flours, noodles and baking
  (04), (09), (31), (44), (72), (73)

- Fodder, processing
  (30)

- Foodstuff, additives and dyes
  (04)

- Foodstuff, industrial equipments
  (16), (18), (19), (26), (38), (39), (44)

- Fruits and vegetables, dried and preserves
  (09), (12), (18), (44)

- Fruits, candies and pulps
  (06), (09), (16)

- Fruits handling (selecting, classifying, packing, conservation)
  (09), (24)

- Fruits, juice extraction
  (04), (06), (09), (12), (24), (26), (40), (42), (43), (73)

- Grains, processing (wheat, corn, beans, rice, sorghum, soya bean, sunflower, coffee, etc)
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- Grains, storage
  (09), (21), (37)

- Internal combustion engine boring (recuperation)
  (66)

- Leather, footware
  (65)

- **Leather, finishing**
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- **Livestock feeds**
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- **Margarine, vegetal fats**
  (16), (42)

- **Mattresses of polyurethane foams**
  (71)

- **Meat and meat products**
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- **Milk powder**
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- **Minerals, metallurgy-engineering consulting services**
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- **Mineral oils, recovery**
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- **Packing (including packing for foodstuff)**
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- **Paints**
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- **Paper**
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- **Pasteurization**
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- **Pharmaceutical products, industrial equipments**
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- **Plate working shops**
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- **Porcelane tableware**
  (53)

- Poultry industry
  (21)

- Red clay ceramic (bricks, roofing tiles, floor tiles, drain pipes)
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- Rubber and plastic products (technical pieces)
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- Sanitary ceramic
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- Seeds processing
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- Slaughter houses (cattle, hogs, goats, poultry)
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- Soap
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- Tannery
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- Textile industry, garments
  (11)

- Textile industry, finishing
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- Textile industry, knitwear
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- Textile industry, plant environment conditioning
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- Textile industry, spinning
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- Textile industry, weaving
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- Tires (for industrial and agricultural vehicles)
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- Tires, re-treading
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- Vegetable oils, hydrogenation
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- Vegetable oils, processing (soya, palm, copra, etc)
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- Wood processing industries, consulting
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- Wood processing, carpentries and cabinet-making
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- Wood processing, mechanical pulp
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- Wood processing, veneers and plywood
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- Wood preservation
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- Wood processing, sawmills
  (15), (61), (64)

(*) Figures into brackets identify name of entity listed in the Participants List (page 10).

INDUSTRIAL PROFILES

RED CLAY CERAMIC PLANT

RED CLAY CERAMIC PLANT

1. INTRODUCTION

Red clay ceramic products comprise bricks, blocks, tiles, floor tiles and drain pipes.

Clay ceramic plants are interesting industries for developing regions for the reasons mentioned beneath:

- the products afford sound characteristics of heat and sound insulation, besides being fireproof;
- the factories are labor-intensive;
- the raw materials and fuels can be obtained on the spot;
- the equipment is strongly built and requires little maintenance

Clay ceramic products generally cannot stand the added cost of transportation to long distances, hence these plants should serve the local market.

The raw material (clay) also needs to be obtained in the vicinity of the plant. Clay must, moreover, be properly selected for manufacture of brick and especially roof tiles of good quality.

The furnaces or kilns can use as fuel lumber, coal, charcoal, gas or oil.

Normally, subject to inquiry, equipment manufacturers offer:

- analysis of clays and recommendations on their use;
- assistance by specialists for preliminary evaluation and aid in preparing feasibility studies.
- technical assistance during erection and start-up of the machinery;
- training of labor on the spot and/or in Brazil;
- technical assistance after start-up.

In accordance with this profile the factory produces only brick and roof tiles.

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2. CHARACTERISTICS

Perforated brick (with 8 holes) measuring 10x20x20 cm, with unit weight of 3.7 kg (raw) and 2.8 kg (after roasting).

Colonial type pressed roofing tile, 50 cm long by 20 cm wide, with unit weight of 3.0 kg (raw) and 2.3 kg (roasted).

- Capacity: 1,872,000 bricks per year
  288,000 roofing tiles per year

3. PROCESS FLOW SHEET AND LAY-OUT

See appended drawings

4. EQUIPMENT

- Box feeder
- Clay disintegrator (or disintegrator and separating mill)
- Mixer, with or without filter (to add water to paste).
- Lamination unit (to homogenize paste)
- Vacuum extruder
- Manual (or automatic) cutter
- Conveyor belts
- Roofing tile press
- Equipment for artificial driers:
  - blowers;
  - hot air generators;
  - exhaustor;
  - metal cocks;
  - electric switchboard;
  - shelving for brick.

- Equipment for furnaces
  - burners (if fuel is coal, charcoal, gas or oil)
  - exhaustors
  - nozzles, valves, etc.
  - metal cocks.
  - hardware

./.

- Hand-drawn transporting pipes
- Wooden lattices for supporting tiles

5. INVESTMENT

Civil works and facilities

	US$
- Shed and floor (*)	222,800
- Machinery bases	4,400
- Electric control house and water tank	3,500
- Furnaces, stacks and drying chamber	101,700
- Offices	10,500
- Electrical network and distribution wiring	65,000
- Maintenance workshop	15,000
	422,900

Machinery and equipment:

- Charge preparation and extrusion	76,400
- Drying	30,000
- Firing (using lumber as fuel)	10,400
- Handling	
1 tipping truck	25,000
1 loading shovel	50,000
1 light truck	10,000
T O T A L	624,700

(*) Local construction, amount involved being subject to considerable variations from area to area.

Area required:	general plot (170 m x 100 m)	17,000 m²
	plant (120 m x 73 m)	8,760 m²
	roofed-over area (75 m x 45 m)	3,375 m²

6. TECHNICAL COEFFICIENTS OF PRODUCTION

- Raw materials 33.3 tons/day (240 days per year)
- Lumber 7.03 m³/day (360 days/year)
- Energy 700 KWh/day

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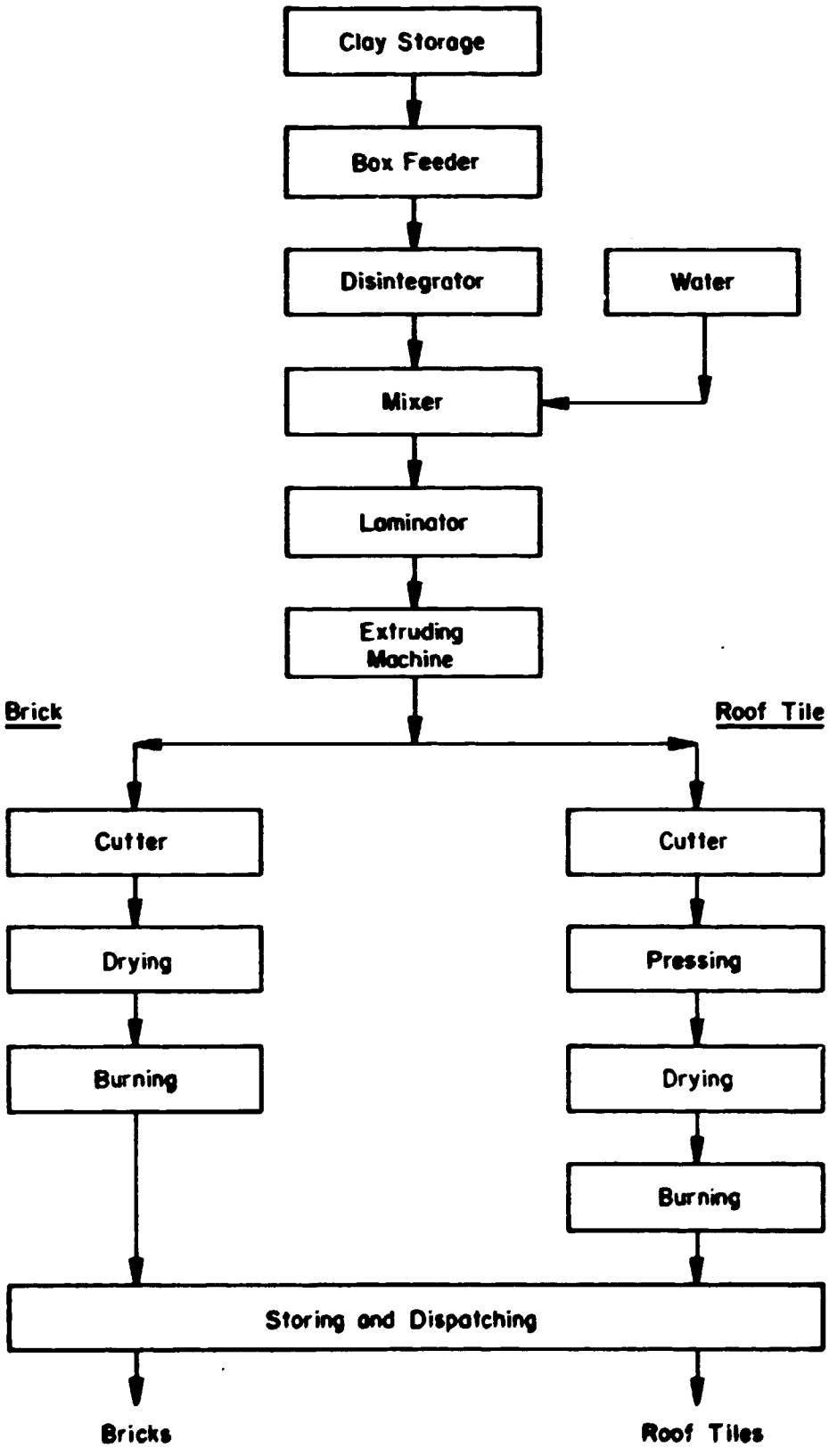
7. LABOR

Skilled	8 workers
Unskilled	35 workers
Management	5 workers
Total	48 workers

8. EXPERIENCE

There are about 5,000 brickmills in Brazil operating with machinery and equipment produced by local industry. Machinery and equipment manufactured in Brazil are also in operation in a number of countries in Latin America and in certain African nations as well.

PROCESS FLOW CHART



SAWMILL

SAWMILL

1. CHARACTERISTICS

Capacity: 40 m^3 of hardwood logs or 80 m^3 of softwood logs

Output: 20 m^3 of sawn hardwood lumber or 56 m^3 of sawn softwood lumber per day.

The lower density species (soft wood) are generaly straighter and more cylindrical, making for a higher degree of utilization.

Sawn planks and boards as put out by the sawmill find a ready market and can also be stored in the open air.

Kiln-drying, however, betters the physical properties of the lumber and is a preliminary operation essential to proper processing.

Better prices are obviously obtained for the dried lumber, quite apart from the resultant savings in transportation.

It is possible to generate captive energy setting up a thermo-electric plant (steam engine unit). The unit basically consists of a furnace, a boiler, a steam engine and a generator. The furnace burns as fuel sawmill residues and even rice husks.

2. EQUIPMENT

- Sawmill
  - . band saw unit with drive wheel 1.35 m in diameter (1)
  - . Capstan jack for logs (1)
  - . Circular edging saw (1)
  - . Circular saw, for processing odd pieces of lumber (1)
  - . Pendulum trim saw (2)
  - . Blade sharpening unit with accessories (1)
- 240 HP steam engine unit
- Kiln

(Figures in brackets indicate required amount of equipment).

3. LAYOUT AND FLOW-SHEET

(see appended drawing)

4. LABOR

- sawmill	14 workers
- Log and plank handling yard	10 workers
- steam engine and kiln	6 workers

5. OTHER INFORMATION

- Installed power required:	200 KVA
- Areas:	
. Sawmill	500 m²
. Other departments	500 m²
. Log yard	1,000 m²
. Sawn lumber yard	1,000 m²
- Operating shift:	10 hours per day

6. INVESTMENT (FOB port of shipment)

- Sawmill equipment	US$ 43,000
- Steam engine (optative)	US$115,400
- Kiln	US$ 35,000

NOODLE FACTORY

NOODLE FACTORY

1. CHARACTERISTICS

Production capacity: 1,200 to 1,500 kg of noodles per eight-hour day.

Approximate production: 50% of "cut" type noodles (spaghetti)and 50% "long" type noodles.

2. EQUIPMENT

Pneumatic flour feed unit
Flour mixing unit
Automatic extruder
Dough extrusion moulds (ten units)
Vaccum station
"Trabato" (preliminary drying of cut dough)
Dough extender bench
Dough pre-drying gallery
Automatic drying units (four units)
Trolleys for extended dough batches (16 units)
Trolleys for cut dough batches (16 units)
Seives for cut dough batches (600 units)
Rods for extended dough batches (800 units)

3. INVESTMENT

Equipment (FOB port of shipment) US$ 75,000

Figure does not include shed, foundations, electrical and plumbing networks, furniture and fixtures. Erection supervision alone is included.

Roofed-over area: 225 m²

4. LAY-OUT

(see drawing).

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5. LABOR

Manufacture:	2 workers
Drying:	1 worker
Packaging:	3 workers
Dispatching:	2 workers

6. CONSUMPTION OF UTILITIES

Energy for motors and heating resistors: about 100 KVA of installed power required.

Heating can alternatively be provided by means of steam or hot water.

7. COMMENTS

Noodle factory can be an interesting project for developing countries when using mixed flour (defated soya bean flour, corn flour, manioc flour, etc). Therefore, this project can be coupled with a manioc or corn flour mill, or with a soya bean milk plant, in which soya bean flour is a by-product.

PAPER FACTORY

PAPER FACTORY

1. CHARACTERISTICS

Small capacity (8 to 10 tons per day) paper plants are aimed at serving the local market. Such plants can produce both plane paper, used mainly for packing, or toilet paper.

They are easy to install, do not require skilled labor for their operation and produce at competitive prices, since they do not need raw materials to be hauled from long distances (consuming paper trimmings and scrap paper). These plants have no unfavorable impact on the local ecology.

The raw material is recycled paper. If the paper plant is to be the first of its kind in the locality, a system will have to be set up for collecting paper scrap, mainly from government offices, printing plants and homes.

2. PRODUCTION PROCESS

The process of paper manufacturing comprises the following basic operations:

a) receiving and stock-piling of paper scrap
b) screening of paper scrap
c) preparation of paste
d) manufacture of sheets in jumbo rolls
e) re-winding into rolls about 10 cm in diameter
f) cutting and packaging rolls
g) storing rolls
h) distribution

(See attached flow sheets)

Lay-out

(See appended drawing)

3. INVESTMENT

Fixed investments for equipment to prepare paste, papermaking machine and ancillary units (excluding erection) amounts to approximatelly US$ 1,050,000.

4. TECHNICAL FACTORS

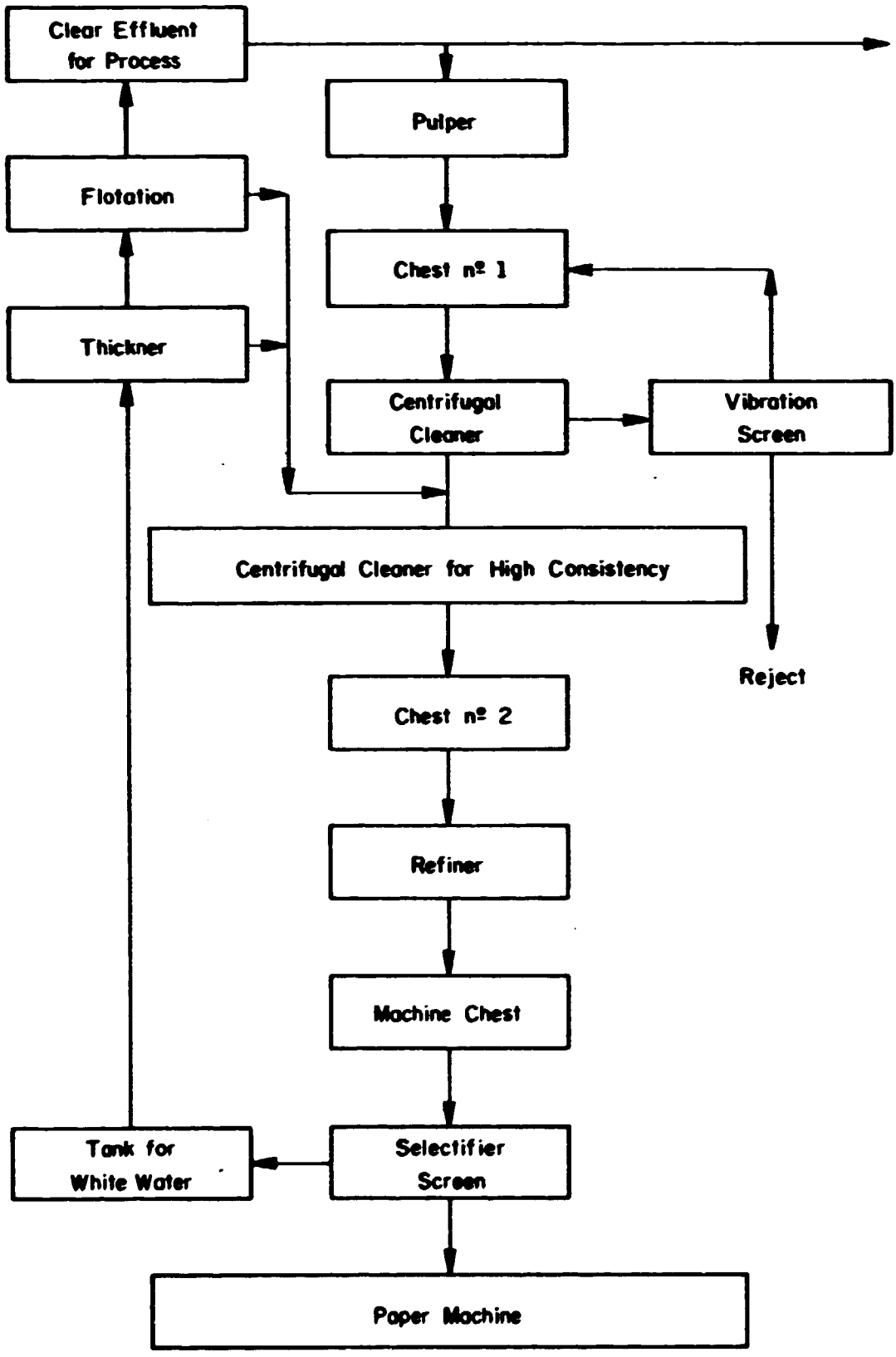
Electric power	400 KVA
Water	50 - 70 m^3/hour
Steam	1000-1200 kg/hour

5. LABOR

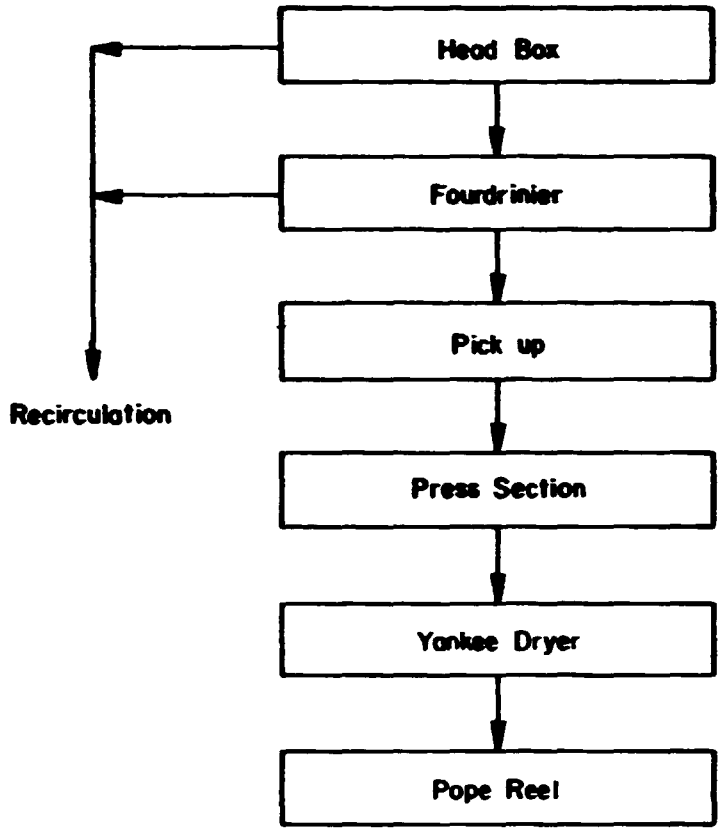
Process phase	Labor qualification	Number of people	Number of shifts	Total Labor
1. Paste preparation	Operators, helpers	3	3	9
2. Paper machine	Operators	2	3	6
3. Finishing	Cuters, packers	20	1	20
4. Boiler	Operator	1	3	3
5. Maintenance	Mechanic, electrician	2	1	2
6. Plant Manager	Supervisor	1	1	1
7. Sales	Salesman	1	-	1
8. Supply	Purchaser	1	1	1
9. Accounts Dep't	Accountant	1	1	1
10. General Services	Helper	1	1	1
11. Secretary	Typist	1	1	1
12. Helpers	Helper	1	1	1
13. Main entrance	Helper	1	3	3
T o t a l				50

SIMPLIFIED PROCESS FLOW CHART

1-STOCK PREPARATION

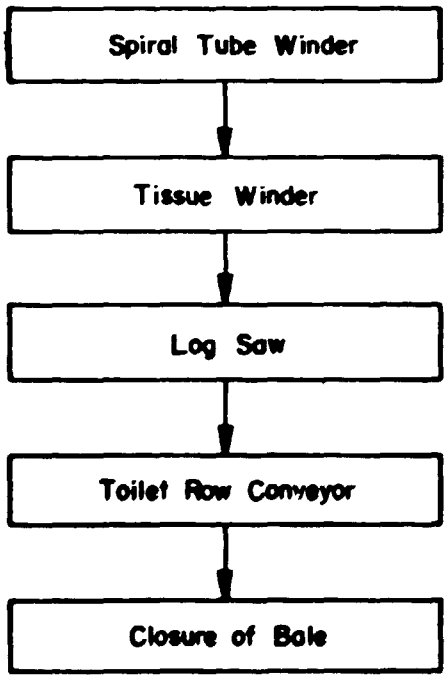


2 - PAPER FABRICATION

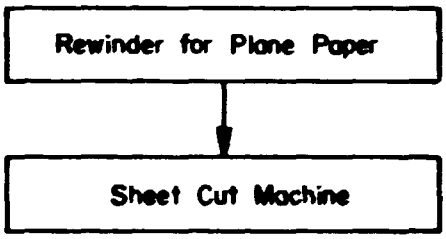


3 - PAPER FINISHING

SANITARY PAPER



PLANE PAPER



SOYA BEAN MILK PLANT

(THE MECHANICAL COW)

SOYA BEAN MILK PLANT

(THE "MECHANICAL COW")

1. Introduction

Soya beans stand out as one of the most important and least expensive sources of protein. Production costs are low, the product is easy to grow, and regular harvests, with a rapid growing cycle, are available around the entire year. The percentage of protein exceeds that of most known foods, and the main vitamins and mineral salts required for human nutrition are also present.

Soya beans disintegrate in boiling water and afford a protein extract easy to obtain and of nutritive value equal to that of the original beans. Soya bean milk affords considerable similarities with cow's milk and human milk, in terms of composition. The taste is pleasant, due to the elimination of the enzyme lipoxide.

2. Characteristics

Capacity: soya bean milk: 200 liters/hour
soya bean flour: 15.4 kg/hour (4% humidity)

Yield: 8 liters of milk/kg of soya

Raw materials: Soya: maximum humidity 14%
beans harvested up to 1 year previously

Water: potable, suitable for human consumption

3. Production process

(See lay-out)

a) Preparation of raw materials

Basically comprises the operation of husking the beans.

b) Maceration

This is done in macerating tanks, in which the beans absorb water and swell up to about three times their original size.

c) Crushing

The macerated beans are treated with hot water (at 95°C) and are crushed in the trituration unit, in which separation of the solids soluble in water takes place, i. e., of the soya bean milk itself. From the trituration unit tank, fitted up to receive ingredients such as aromatic essences, bicarbonate, salt and sugar, the soya bean milk is transferred to the filter.

d) Filtering or centrifuging

In this stage the soya bean milk is separated from the residue not soluble in water. The humid residue is what gives rise to the soya bean flour, as will be seen later in this report. The soya bean milk may then be fed into a reserve tank.

The filter consists of a metallic basket supporting a 100 mesh nylon screen, in which the insoluble solids are separated by centrifuging.

e) Ultra-pasteurization

From the reserve tank the milk is pumped to the ultra-pasteurizing unit, in which it is subjected to heat treatment at 125°C for two minutes.

The heat treatment ensures total destruction of the micro-organisms normally present in the milk.

f) Pre-chilling

The milk is pre-chilled, and the temperature goes down from 125°C to 25°C. At that temperature the milk can be packaged for immediate consumption (up to 20 hours after packaging).

The heat given off during the pre-chilling phase is utilized to heat the water that will be used in the crushing phase, thus saving energy.

The entire process, up to this point, with the exception of the husking, takes place in a compact unit called the "processing unit" or the "mechanical cow".

g) Cooling

If the milk is to be held for a longer period, it must be cooled to about 8°C to 10°C, in which case it has a shelf life of up to five days.

h) Packaging

In the packaging unit the milk is processed without contact with workers' hands.

Soya bean flour

During the centrifuging of the crushed soya beans, the liquid phase gets to be separated from the solid phase. The solid phase, at 77% humidity, gives rise to the soya bean flour.

The humid flour is removed from the basket of the centrifuge, and pressed by hand, and then dried at 100°C, after which it can be stored at ambient temperature for a period of up to one year.

The flour can be used as a livestock feed or for human consumption (even in bakeries).

4. Equipment

- Processing unit, comprising:
  - . water heater with capacity of 60 liters
  - . trituration unit, capacity: 300 kg/hour
  - . centrifuge, capacity: 1000 liters/hour
  - . ultra-pasteurizer, capacity: 200 liters/hour
  - . pre-chilling unit
- Cooler
- Drier, consisting of drying chamber, cyclone, hot air generator, hydraulic press and electric switchboard
- Soya bean peeler, capacity: 200-300 kg/hour of soya beans
- Packaging unit

5. Investment

- Major items of equipment (listed above), plus spare parts, packaged for shipment by sea, FOB port of shipment — US$ 55,000
- Auxiliary equipment (compressor, freezers) — US$ 2,000
- Electrical networks and plumbing — US$ 3,000
- Building — US$ 12,000

Building lot for plant and costs of erecting equipment not included.

6. Technical factors

Water: 1.5 liters/liter of soya bean milk

Energy: 0.14 kw/liter of soya bean milk

Labor: 1 supervisor
2 operators
1 assistant

Covered area:		
	processing:	44 m^2
	storage of inputs:	34 m^2
	shipment:	7 m^2
	administration:	27 m^2
	T o t a l:	112 m^2

TANNERY

TANNERY

CAPACITY: 100 to 150 skins per day

PROCESS DESCRIPTION: (see lay out)

Tanning starts with the liming tan pit, purpose of which is to strip the hair from the hide and destroy the hair. The liming operation, from which the hides emerge in a swollen state, is followed / by the fleshing operation, purpose of which is to eliminate the greasy material adhering to the hide. This is done in the fleshing machine.

After fleshing, the hides are split. The respective operation consists of separating the hide into two layers parallel to the / grain. Two separate layers are generally obtained, the upper one being known as the "grain" (or, more usually, "full grain") while the lower one is termed the "crust".

The above operations are followed by tanning, purpose of which is to render the material stable and immune to decay. This is done in tan pits.

This sequence entails drying (by wiping), on the drying machine. This is a mechanical operation intended to remove excess liquid from the tanned leather. After drying, the leather must be left at rest for normalization of the fibers. After the period of rest, a / start is made on reducing or calibrating. This is done on calibrating machines which ensure uniform adequate thickness over the entire area of the respective pieces of leather.

At this stage the material is known as "wet-blue leather".

The skins then go to the retanning units. Operations on the finished leather may also take place in these same tanning pits.

Retanning consists of consolidating and rectifying the leather grain. After this operation the leather goes back again to the drying machine, as described above.

After the drying process is completed the leather is stretched, the purpose being to open up the folds of the skin and reduce excess

water. The skins then go to the plate dryers, eliminating further / water ang giving a better appearance to the grains, besides elimina ting any defects caused by ticks. The skins are then sent to the / toggling stage, purpose of which is to complete drying. Use of this unit is extremely valuable in tanneries, when properly applied, because it permits a considerable increase in the size of the pieces.

The dry leather is now ready to be painted in the painting / tunnel and then printend in the printing machine. It is then in a state for storing and shipment.

A sole leather section can be added to the plant.

Sole leather hides are processed in the Sole Section. Here the hides are tanned, greased and stretched, and then dried in the drying oven. Sole leather also passes through the sole calander before being sent to the shipping department.

EQUIPMENT

Section for cowhide under chrome (for 100-150 skins per day)

- Liming drums
- Fleshing machine
- Splitting machine
- Drying machine
- Tan pits for tanning (2 pieces)
- Calibrating machines
- Tan pits for retanning
- Plate dryers (Secotherm) (3 pieces)
- Samming machine
- Toggling
- Sanding machine
- Painting tunnel (with manual pistols)

Section for sole leather (for 100-150 sole leathers per day)

- Tan pits for sole leather (3 pieces)
- Pits for greasing (2 pieces)
- Stretching machine
- Drying oven
- Calander for sole leather

CHEMICAL CONSUMPTION

An average figure, only for cowhide under chrome, would be / US$ 36,000 per month.

INVESTMENT

Machinery and equipment (FOB port of shippment)

- Section for cowhide	US$ 186,000
- Section for sole leather	US$ 73,000

Man Power

50 workers in 8 hours/day shift (60 workers if sole leather section added).

ALCOHOL MICRO DISTILLERY

ALCOHOL MICRO DISTILLERY

1. CHARACTERISTICS

Capacity: 5,000 liters of alcohol (ethanol) per day

Raw material: sugar cane

TFS (min.) 14% (total fermentable sugars)

Fiber content: (max.) 12.5%
(78 to 83 tons of cane to produce 5,000 liters of ethanol)

Product: hydrated alcohol (96°G.L. at 15°C) (first grade alcohol)

Specific gravity at 20°C: 0.8073 to 0.8150

Alcohol content at 20°C, % by weight: 93.2 ± 0.6

By-products: second grade alcohol (2 to 5% of output of first grade alcohol)

fusel oil (1 to 2 liters per 1,000 liters of ethanol)

stillage (2,800 to 3,000 liters per hour, to be returned to ground as fertilizer)

cane bagasse (1,500 kg/hour, 51% humidity, to be used as livestock feed supplement)

2. DESCRIPTION OF PROCESS (see simplified flowsheet)

A - EXTRACTION AND GRINDING

A four-roll mill is used with complete imbibition, which permits extraction to the extent of some 65%.

The sugar cane is fed in by means of a fixed feed table and / cane chopper, with semi-mechanized feed arrangements. The juice obtained is collected in a bin made of stainless steel sheet, located underneath the mill, and is screened to separate the ' finely divided bagasse and then sent for fermentation.

B - FERMENTATION

The process used is the conventional type of open vats, cooled on the outside with water, the ferment being decanted off to ' separate it from the fermented juice (wine).

The "wine" thus obtained is pre-heated by means of stillage in a counter-current arrangement, within a liquid/liquid heat-exchanger and then pumped to the distillation column.

C - DISTILLATION AND RECTIFICATION

The required steam is obtained by using a direct flame heater, in which the stillage derived from the distillation process is circulated and the fuel being the sugar-cane bagasse.

The main advantages of this system are high energy efficiency, with consequent reduction in consumption of fuel and reduction in the ultimate volume of stillage produced.

The reason is that since the boiler drum is fed with stillage at 105°C, fuel has to be consumed merely to produce the latent heat of vaporization, and since the steam supplied to the / columns is produced from the stillage itself, the volume involved is greatly reduced.

The fermented juice, known in the trade as "wine", is pumped ' through the liquid/liquid heat exchanger to the distribution ' tray at the top of the distillation column.

The wine emerges from the liquid/liquid heat exchanger at boiling point and descends the column in counter-flow with the / arising stream of steam that goes up through the perforated ' plates.

On reaching the bottom of the column, the wine, now converted into stillage by evaporation of the alcohol, circulates through the heater, where a part of the water is evaporated, thus producing the steam required to run the column.

The surplus stillage passes through the heat exchanger in which it is cooled, thus pre-heating the "wine", and is discharged ' at practically ambient temperature.

The mixture of alcohol vapor and steam passes from the top of the distillation column to the base of the rectification column along the flegma tube. This mixture of vapor and steam rises through the filler rings of the rectification column on / counter-current with the flowing down alcohol and condenses in the condenser mounted at the top of the column.

In the rectification column, the hydrated alcohol with a minimum boiling point, corresponding to the azeotropic mixture of alcohol and water, is collected in the alcohol intake tray, / from which a part is removed through the alcohol cooler for the tanks.

The remainder, consisting of about 80%, goes back to the column and runs down through the filler rings.

The water and a part of the alcohols, transferred to the rectification column as "flegma" are collected at the base of the column and return to the "wine" tank, being recirculated in / the process.

The "wine" feed flow and alcohol production flow are controlled by two valves mounted on the control panel, so as to obtain the kind of alcohol required.

The liquid is withdrawn continuously at two collection points at suitable locations and this liquid is then diluted and sent to the fusel oil decanting unit. The fusel oil is removed continuously and the remaining mixture is recirculated together with the "wine".

The equipment provides for collecting second grade alcohol as well as products from the head of the column and fusel oil.

3. EQUIPMENT

- 01 Fixed feed table
- 01 Sugar cane feed conveyor
- 01 Sugar cane knife (chopper)
- 01 Four-roll sugar cane mill
- 01 Imbibition unit
- 01 Centrifugal pump (for transfer from the cush-cush to the static screening unit)
- 01 Centrifugal pump (for transfer from the screening unit to the vats)
- 01 Juice screening system
- 01 Static screening unit
- 08 Vats (capacity 14 m^3 each), with accessories
- 01 Distillation column
- 01 "Wine" purification sector

- 01 Rectification column
- 01 Alcohol condenser
- 01 "Head fraction" concentrating column
- 01 "Head fraction" condenser
- 01 "Wine"/stillage heat exchanger
- 01 Cooler for first grade alcohol
- 01 Switchboard
- 01 Heater/evaporator (reboiler)
- 01 Automatic column pressure controller
- 01 Fusel oil separation/decanting unit
- 01 Tank for circulation of caustic soda
- 01 Centrifugal pump for transferring "wine" to column
- 01 Centrifugal pump for cooling vats
- 01 Centrifugal pump for transferring alcohol to storage tank
- 01 Blower for furnace
- 02 Alcohol measuring tanks
- 01 Water cooling tower
- Laboratory instruments
- 01 Electric switchboard
- 01 Tank for storage of alcohol (100 m^3 capacity)
- Supporting and roofing structures

4. LABOR

5 workers per eight-hour shift

- 01 foreman
- 01 fermenter/distiller
- 03 assistants

5. INPUTS

Processing water: 2 m^3/hour

Cooling water (closed circuit): 12 to 14 m^3/hour

Electric energy: installed power 50 KVA

Chemical products:

- Ammonium sulphate: 1.5 g/liter of alcohol
- NPK 0.75 g/liter of alcohol

- Sulphuric acid: 0.30 ml/liter of alcohol
- Penicillin: 0.006 mg/liter of alcohol
- Yeast (at start of operation)

6. INVESTMENT

	US$
- Equipment (F.O.B. port) (includes mechanical erection)	222,000
- Erection (labor)	8,000
- Transformer, refractory bricks	11,000
- Industrial shed	10,000
Estimated total	251,000

- Built-up area 320 m^2
- Total area 10,000 m^2
- Sugar cane planting area: 240 hectares (2.4 million m^2)

VEGETABLE OIL PLANT

VEGETABLE OIL PLANT

Characteristics

The profile presented here is for a vegetable oil plant running merely on a basis of mechanical extraction (no solvent extraction). The unit is therefore indicated for processing grain with a high oily content, such as peanuts, cotton, sunflower, castor seed, palmiste, etc. It could also process various different types of seeds each one during a certain period of the year and hence reach a high level of utilization. In this case, of course, crude oil tanks would have to be provided for the various types of oilseeds processed.

There is another source of flexibility, namely that the cake may contain as much as 5% to 12% of residual oil. Cake with 5% of oil can be used for livestock feeds (except that from castorseed, which is used as fertilizer), whereas cake with 12% of oil can be extracted with solvent to provide additional quantities of oil.

Extraction by solvent can be carried out in centralized units receiving rich cake (12% of oil content) from a number of smaller plants. The latter alternative, however, calls for careful planning, because some rich cakes (those from cottonseed and castorseed) have to be processed within a short period of time, being liable to spoil (become rancid).

Capacity

The plant has capacity for processing 60 tons a day of oil seeds, giving a cake that contains 5% of oil.

Capacity can, however, rise to 100 tons a day, if the cake produced still contains 12% of residual oil.

As will be seen later in this study, provision has been made for four presses. The plant might possible start operations with just one or two presses. But the reduction in the initial investment would not be very considerable because the equipment downstream of the presses is not amenable to splitting up; in other words, the mills, filters, pumps, etc., do not vary much in price as a function of the capacity, so they would have to be designed to cover the full ultimate capacity of the plant.

In terms of oil seeds processed, crude oil and cake obtained, ' capacity would be as indicated beneath:

Capacity of plants for various oilseeds

Raw materials	Oilseed, tons/day		Crude oil, tons/day		Cake, tons/day	
	cake, at 5%	cake, at 12%	cake, at 5%	cake, at 12%	cake, at 5%	cake, at 12%
Peanuts	60	100	24.0	22.0	36.0	36.0
Cottonseed (1)	60	100	16.8	15.6	43.2	44.4
Sunflowerseed(2)	60	100	22.8	21.2	37.2	38.8
Castor seed	60	100	25.6	23.6	34.4	36.4

(1) Pulp only

(2) Based on cold climate sunflower seed (about 40% of oil content)

Description of process (see diagram)

The raw material is transported direct from the warehouse by a screw conveyor to a cleaning screen. After cleaning, the seeds go to a hammer mill from whence they are taken to the cooking unit, and afterwards drop onto the press. The oil obtained by pressing runs into the floor tank and is then pumped to the homogenization unit. From / there it is taken to the filter-press, and subsequently goes to another floor tank, being finally pumped to the storage tanks.

A bucket conveyor takes the cake from the press to a hammer / mill where it is crushed and then goes to the bagging department.

Investments

Equipment and materials:

- screw conveyors
- continuous-operating expeller press units, with individual cookers (4)

- hammer mills (2)
- floor tanks (2)
- storage tanks, 100,000 liter capacity (2)
- gear pumps
- homogenizer
- filter-press
- mechanical bucket conveyor
- silo for bagging cake
- steam boiler (1,000 kg/hour of steam)
- all necessary electric motors
- all necessary steel structures

Each group of expeller presses has capacity for processing 15 to 25 tons per day, dependent on whether the residual cake contains 5% or 12% of oil.

The equipment is strong, easy to operate with semi-skilled labor and requires little maintenance.

The cost of the equipment and materials, as described above, is US$ 300,000 (F.O.B. port of shipment).

That figure does not include civil works or erection.

Roofed over area: 2,000 m^2

Total area: 35,000 m^2

Labor

Production: 38 workers (*)

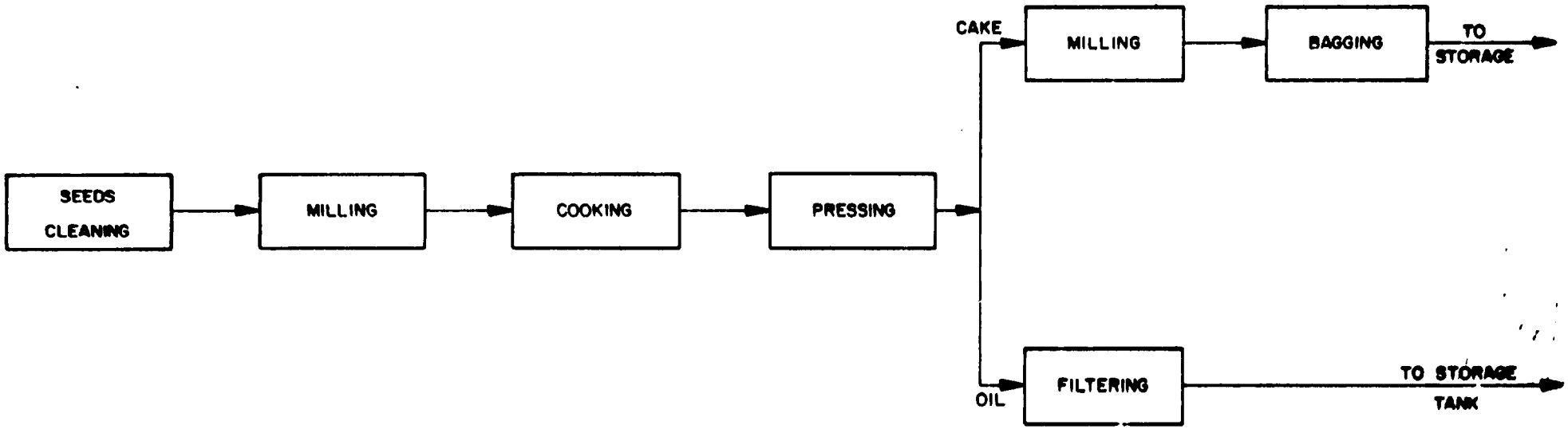
Administration: 7 workers

Total: 45 workers

(*) The factory manager, chemist (technical level) and the head of the maintenance workshop would have to be of the skilled labor category.

VEGETABLE OIL PLANT

SCHEMATIC FLOW DIAGRAM



MILK PASTEURIZATION PLANT

MILK PASTEURIZATION PLANT

Capacity

The plant described can process 1,000 liters of milk per hour.

Description of Process (see simplified flowsheet)

The raw milk from the intake tank flows to the equilibrium tank (1), in which it is maintained at constant level by the float valve (2) inside the tank.

The pump (3) then pumps the milk to the regeneration section (5) of the plate heat exchanger, passing first of all through the flowmeter (4) which is used to hold the flow rate constant.

In the regeneration section, also referred to as the heat recovery section, the raw milk entering into the plate heat exchanger receives heat from the pasteurized milk emerging from the apparatus and, as a result, is pre-heated; the pasteurized milk emerging from the plate heat exchanger transfers heat to the raw milk just entering the device and is conversely itself cooled down.

On leaving this section the milk is standardized in a centrifuge (not indicated on the flow sheet) and proceeds to the final heating section (6) where it is heated up to the pasteurization temperature established by law.

As pasteurization implies the action of the binomial temperature plus time, the milk is sent to the retarding unit (7) in which it is held for the period of time also established by law (usually 15 seconds).

After the retarder comes the flow return valve (8), which automatically returns the milk to the equilibrium tank if it does not happen to be at the proper temperature (an underheated batch might otherwise contaminate milk already pasteurized). If this does not occur, the already pasteurized milk is chilled first in a counter-current process in section (5) as described previously, and later by means of cold water in section (9); final chilling is effected by iced water in section (10). The milk, on emerging from the plate heat exchanger, has its temperature indicated by the thermometer (11) and then goes to the storage tanks which in turn feed the packaging units.

The temperature of pasteurization and the possible operation of the return valve (8) are recorded on the instrument panel (15) on a continuous and automatic basis.

The switchboard contains not only the temperature recorder but also the switches for the pumps handling milk, hot water, cold water and iced water, and may also contain the protective switches and / start-up devices for the pump electric motors.

The hot water for final heating is generated in tank (13) and circulated through the plate heat exchanger by pump (12). The temperature of the hot water is maintained by injecting steam via a diaphragm valve (14) that is controlled in turn by an automatic temperature controler mounted in the switchboard (15).

Equipment

- Plate heat exchanger for raw milk;
- Insulated tank for storage of cooled raw milk, with accessories;
- Sanitary centrifugal pump;
- Pasteurization unit:
  - . Equilibrium tank
  - . Sanitary centrifugal pump
  - . Flow control valve
  - . Plate heat exchanger
  - . Vertical tubular retarding unit
  - . Automatic return valve
  - . Hot water generating unit
  - . Platform for supporting the unit
- Instrument panel (switchboard)
- Piping (pipes, connections and gate valves)
- Isothermal tank for storing pasteurized milk
- Sanitary centrifugal pump for packaging unit
- Sanitary centrifugal pump for cleaning operations

Besides the above-mentioned processing equipment items, the / following items are also required:

- Complete system for generating iced water with capacity for 8,000 liters per hour at a temperature of 1°C.

- Generator for saturated steam at 105°C or generator for hot water at 80°C, with capacity for 3,000 liters per hour.

There will also be a need for a small air compressor (140 li - ters per minute at a pressure of 8 kg/cm^2) and possibly a step-down' transformer for electric current to drive the motors (220/380 volts).

Investment

Process equipment	US$ 47,000
Iced water generator	US$ 18,000
Hot water generator	US$ 15,000

CONCENTRATED CITROUS JUICE PLANT

CONCENTRATED CITROUS JUICES PLANT

CHARACTERISTICS

Capacity: 5.5 tons per hour of fresh fruit (oranges)

Product: 418 liters per hour (528 kg/hr) of concentrated juice at 58^{o} Brix

By-products: 22 kg/per hour of essential oil and
545 kg/hour of livestock feeds

DESCRIPTION (see simplified flow-sheet)

The industry is composed of the main sections listed beneath:

1. Receiving and stockpiling of raw materials
   - Weighing
   - Discharging, analyzing and storing in silos

2. Preparation of raw material
   - Discharging of silos, pre-selection, washing and calibration into different sizes
   - Extraction and refining of juice

3. Concentration
   - Concentration, pasteurization and recovery of aromas

4. Freezing
   - Freezing and final packaging

5. Recovery of by-products
   - Recovery and refining of essential oils
   - Recovery (drying) of residues to obtain pelletized livestock feeds

6. Utilities

OTHER INPUTS (for one twenty-hour day)

Drums for juice, (200-liter capacity)	unit	40
Bags for livestock feeds	unit	240
Lumber or compressed sugar cane bagasse	ton	15
Water, m^3		80
Electric energy, kwh		3300

LABOR

	Number of workers
Administration and general services	28
Production, including laboratory	178 (1)
Utilities	25 (2)
Maintenance	10
Total	241

(1) 138 workers on shift
(2) All on shift

INVESTMENTS

	US$ 1,000
Equipment:	
- for concentrated and chilled juice	1,550
- for recovery of oil	155
- for recovery of livestock feeds	725
- for utilities	380
Total	2,810

The above figures do not include electric materials, or piping for water.

Roofed-over area	5,000 m^2
Total area	20,000 m^2

Comments

1. The above-mentioned plant could also produce, in a blocked - in operation, lemon juice (Tahiti type).

2. Investment is usually rather high because the equipment is ' built of stainless steel.

3. The concentration and cooling sections also represent a large share in the total investment. If the purpose was to produce merely plain juice (not concentrated), bottled for the' local market, the necessary equipment would amount to about' US$ 600,000.

4. This kind of plant is highly sensitive to economies of scale. For the capacity assumed in this profile study, (5.5 tons / per hour of oranges), total fixed investments would be about US$ 4 million. For a capacity about four times as large, on ' the other hand, fixed investments would not even be as much as twice the above figure.