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**ESTABLISHMENT AND DEVELOPMENT OF REGIONAL NETWORK
FOR EXCHANGE OF INFORMATION, EXPERIENCE AND TRAINING
IN PHARMACEUTICAL INDUSTRY**

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CONTENTS

	Page No.
1. Drugs for common diseases	1
1.1. Introduction	1
1.2. Present scenario	1
2. Global situation of drug consumption/production	2
2.1. Availability of drugs	2
2.2. Disease pattern	3
2.3. International drug production and distribution scene.	3
3. Pharmaceutical sector policy and plan	5
3.1. Objectives	5
3.2. Policy issues	5
3.2.1. Drug policy	5
3.2.2. Indigenous production of pharmaceuticals	7
3.2.3. Regulation of prices	7
3.2.4. Essential drugs	8
3.2.5. Traditional system medicines	9
4. Pharmaceutical industry at regional level	10
4.1. Indian experience	10
4.2. Growth of industry in India	10
4.3. Important elements of drug policy	11
4.4. Characteristics and structure	12
4.5. Regional co-operation	13
5. Pharmaceutical industry data base and information centre	13
5.1. Background	13
5.2. Quantification of drug requirements	13
5.2.1. Health data based estimates.	14
5.2.2. Consumption pattern analysis.	14
5.2.3. Relative advantages and limitations	15
5.3. Update on recent developments	15
5.4. Data bank	15
5.5. Bibliographic surveys	16
5.6. National Information Centre for Drugs & Pharmaceuticals (NICDAP)	16
5.7. Regional information centre for drugs & pharmaceuticals	17
5.8. Regional training centre(s) for human resource development.	17
6. Summary & conclusions.	18

**ESTABLISHMENT AND DEVELOPMENT OF REGIONAL NETWORK
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DR PARVINDER SINGH

1. **DRUGS FOR COMMON DISEASES**

1.1. **Introduction:** Drugs are indispensable tools in controlling and curing diseases and improving the health of the people. The drugs known today are capable of treating a large majority of the problem diseases. What is needed is to develop systems which would make optimum use of the resources to make drugs available to all those who need them.

1.2. **Present scenario:** Significant advances in drug research including understanding of disease processes, discovery of new chemical entities, new applications of existing remedies, development of novel drug delivery systems and improvements in technology of manufacture have been made in the past 50 years or so. Thus, drugs have been discovered for most of the common diseases which afflict mankind. As a matter of fact, developments in the field of anti-infectives have made it possible to eradicate small-pox from the globe and to reduce mortality and morbidity to an extent that in most developing countries, the inadequate reduction in birth rates has started creating serious problems due to population explosion in Third World countries. Similarly, most other bacterial, helminthic and some fungal diseases are under control because of availability of effective drugs. Remedies for controlling dreaded diseases like leprosy and tuberculosis are at our disposal. Most inflammatory and allergic disorders as well as psychiatric conditions are controllable. Good analgesics, anaesthetics, anti-hypertensives and other cardiovascular drugs as well as remedies for controlling respiratory diseases have been added to our armamentarium. New generation of vaccines and biotechnology-based products are helping us improve longevity and quality of life. It is rather ironical that inspite of such remarkable progress in the medicinal field there has not been comparable improvement in morbidity and mortality figures world wide. The main reason for this seems to be our failure to provide the benefits of this knowledge to almost 50% of humankind living in the Third World countries. This challenge must be met effectively and soon if the target of Health for All by 2000 AD has not to remain merely a mirage.

2. GLOBAL SITUATION OF DRUG CONSUMPTION/PRODUCTION

- 2.1. **Availability of drugs:** The available drugs are not equitably distributed. According to information compiled by the WHO, more than three-quarters of the drugs produced were consumed in 1976 by 27% of the world population living in developed countries. This situation worsened further in 1985 when 75% of the world population living in developing countries consumed only 21% of the world's drug supply. This is what I would call as the "reverse 20:80 situation", summarized in table I.

Table I: Drug Needs of Developed and Developing Countries

	Developed	Developing
% World population	20	80
% Consumption of world production of drugs	80	20
Major drug needs	Cardiovascular Anticancer CNS Antibacterial	Antimicrobials particularly antiparasitic Antifertility drugs and population control devices*

* Condoms are legally recognised as "drug" under the Drugs & Cosmetics Act in India.

This has probably further increased since then because of the relatively faster rate of growth of population in the less privileged parts of the world. Even in the developing countries the underprivileged population living in rural areas, who really need more medical aid, get only a small fraction of the already meagre drug supply. Coupled with this, the poor sanitation and water supply facilities complicate matters still further. The urban areas, where hardly around 25% of the population lives but get almost 75% of the coverage, too do not get full access to the health services to the envisaged extent. It appears that the national health policy

implications rarely percolate down to the health works and to the people. In so far as drug supplies are concerned there is not only inadequate availability of the essential drugs but also faulty distribution of whatever is available. In India, despite price controls and phenomenal growth of the pharmaceutical industry during the past 20-30 years, the availability of modern drugs remains low. This is particularly so in rural and semi-urban areas.

2.2. **Disease pattern:** There is need for increasing production and supply of drugs specially for treating bacterial infections and parasitic disorders like malaria, filaria, amoebiasis, worm infestations, etc in developing countries because these are more common in the underprivileged population on account of poor sanitation and water supply. Similarly, more emphasis should be given to increased availability of drugs for diseases more prevalent in a particular country or region. The disease pattern in India is summarised in table II. Of course, proper attention has to be given to matters concerning nutritional status, environment, sanitation and water supply and above all to steps to control population growth in the shortest possible time frame.

2.3. **International drug production and distribution scene:** A very large proportion of drugs are produced by developed countries of North America, Europe and Japan. The world production in 1988-89 is estimated to be around US \$ 128 billion, the developing countries accounting for hardly 10% of it. On the other hand, the developing countries consumed drugs of almost double this value, i.e., about US \$ 24 billion. The unfavourable balance of payment situation is therefore apparent straightaway. But when one looks at the value of per capita drug consumption in developing countries and compares it with that in the developed ones, the position becomes even more glaring. For example, when Japan, USA, France and UK spent 116.2, 110.5, 80.9 and 41.1 US dollars per head respectively in 1985, the figures for China and India were 4.4 and 2.3 US dollars only respectively. Whereas there has been a sharper rate of increase in per capita consumption of drugs in North America and Japan, the per capita consumption remained almost static during the decade 1976-85 in developing countries. So the developing countries get hit adversely not only financially but also in terms of inadequate availability and consumption of drugs.

It is important to develop a system by which all the information and knowledge concerning drugs is disseminated more widely so that regions and countries poorly served at present get the benefit of the same. The pharmaceutical industry is multidisciplinary and multifaceted. All these aspects have to be stressed in the information and training system to be developed. The main thrust of this presentation will be on the development of such a system for use by the Third World countries.

Table II: Disease Pattern In India - 1980

Communicable diseases	Morbidity profile
Malaria	6.5 million cases
Filaria	236 million people exposed (33% of population); 18 million people (microfilaria +ve); 14 million people (filarial disease)
Tuberculosis	10 million cases of tuberculosis (25% are AFB +ve); (deaths 60-80 per 100,000)
Leprosy	3.2 million cases (25% lepromat- ous type)
Venereal diseases (STD)	34 million cases
Trachoma	Responsible for 5% cases of blindness and visual acuity less than 6/60
Gastrointestinal disorders:	
Cholera	13,000 cases
Typhoid	230,000 cases; 745 deaths
Amoebiasis	102.5 million cases
Ankylostomiasis	205 million cases.

3. PHARMACEUTICAL SECTOR POLICY AND PLAN:

3.1. Objectives: The welfare needs of the people demand that pharmaceutical sector of a country ensures availability of drugs to all those who need them. This sector's activities include local production of drugs and import of those not indigenously produced; institution of a reliable quality assurance system; creation of an efficient storage and distribution system through distributors, wholesalers and retailers and coordination of the same with the requirements of health services. The pharmaceutical sector thus constitutes a chain, and any break in the chain can lead to disruption of supply of pharmaceuticals to the consumer. A policy for the pharmaceutical sector should, therefore, deal not only with production and procurement but also encompass in an integrated fashion many other interrelated matters which would ensure through appropriate machinery that the benefits of the drugs reach the people in the remotest parts of the country. That is the end to which all the other steps are a means. The main aims for the technology policy for the pharmaceutical sector thus are:

- to ensure adequate supply of drugs at reasonable cost
- to develop indigenous capabilities and a self-reliant technology base
- to establish a dynamic indigenous pharmaceutical industry with an appropriate distribution system.

3.2. Policy issues: To achieve these objectives a proper policy frame-work is required which should be addressed in particular to the following issues:

- Drug policy; incentives for indigenous R&D; self-reliant technology-transfer policy
- Indigenisation of production through state, and private sector

3.2.1. Drug policy: The pharmaceutical sector is amongst the most highly science and technology based endeavours. Its integrated development requires a number of technology inputs which should be welded into a coherent drug policy in consonance with the overall technology policy of the country. This should cover the following:

- Planned and regulated growth of the pharmaceutical industry; linking of packaging and dosage form industry with phased production of drug substances
- Regulation of prices; transfer pricing
- Essential drugs
- Place of traditional system medicines
- Long-term perspective of growth of the industry as a part of the industrial policy; role of private and public sectors; role of foreign vs national private sectors.
- Regulation of foreign investment; foreign sector primarily for high technology areas
- Technology acquisition and technology transfer policy; careful negotiation on use of raw materials, intermediates, production equipment and on exports arising out of technology import; outright purchase vs royalty payment; horizontal transfer arrangement; possible association of R&D institution in agreements for technology import for better technology assimilation
- Promotion of R&D; incentives for indigenous inhouse or sponsored R&D such as tax benefits or preferential licencing for indigenously developed processes or products
- Mechanisms of protection to the indigenous industry
- Organisation of an industrial property bank; terms and conditions for use of this knowledge
- Intellectual property protection issues, particularly patent laws and trade-marks; special provisions for drug industry; product vs process patents; period of protection and compulsory licencing arrangements
- Development of systems for collection and dissemination of information and setting up a training network

3.2.2 Indigenous production of pharmaceuticals: As already pointed out, the production of pharmaceuticals has both an economic dimension and a strategic element; and a balanced perspective of both aspects is necessary while drawing up strategies and plans for this sector. It is often argued that many developing countries are so small and have such meagre resources that they cannot establish economically viable units for production of pharmaceuticals. This is not a wholly correct appreciation of the situation. The manufacture of pharmaceutical products involves a number of distinct stages not all of which require very large production volumes for economic viability. All stages of manufacture need not be carried out at a single location. It is also unnecessary for each country to carry out all operations simultaneously but every country can and should carry out some stages of production in keeping with its resources. For the sake of security of supplies and building up domestic capabilities as well as on balance of trade considerations, it is most desirable for each country to carry out some domestic production. While no country can be self-sufficient in drug production, each country can aspire to establish a self-reliant technology base so that it can manufacture at least its critical requirements. Even though pharmaceuticals are vital for health and the pharmaceutical industry is socially one of the most relevant areas for the public sector, one need not be dogmatic on this aspect. It is however noteworthy that even countries of the socialist bloc are now moving towards privatisation. Private industry should therefore be encouraged to take up pharmaceutical production to the extent necessary.

3.2.3 Regulation of prices: The pricing of drugs is a complicated and sensitive issue and has been the subject of much controversy and debate. Drugs fulfill a critical social need. Majority of the population in developing countries is poor with low buying power. The prices of drugs, therefore, should be kept as reasonable as possible. The drug industry, however, must make adequate profits which would make the exercise remunerative enough to attract fresh investments and also pay for the high R&D expenditure on new development. The price, therefore, has to be a proper balance of these competing demands. Experience in marketing of pharmaceutical products in both the developed and developing countries has shown that prices tend to get raised out of proportion to costs if left totally unchecked. A certain amount of regulation and control on prices is therefore, necessary. A selective price control system starting with essential drugs would be the most practical approach. However, it

would be necessary to provide special incentives to promote higher production of essential drugs, which could be in the form of tax reliefs, removal of local taxes, simpler licencing procedures, etc. For other drugs an overall profitability control may be in order. A careful monitoring of the trends of production and pricing of non-essential drugs, however, is necessary so that unduly high prices are not charged.

Another point to watch is the price of indigenously produced drugs against the international prices; the latter may be lower in many cases. A certain amount of price protection for the indigenous industry would be necessary in the initial stages of establishment of the industry. This could be done through protective duty on imported drugs. Allowing free imports of drugs because these are cheaper in the international market is no solution of the problem as it can hurt the indigenous industry. In many cases, the high input costs account for high costs of the indigenously produced drugs. Efforts should, therefore, be made to reduce the input costs and not allow free imports as the latter will be counter-productive in the long run. Each case must be carefully studied and appropriate decisions taken.

Transfer pricing is a common practice resorted to particularly by multinational companies when they conduct business on a world wide basis. It is, therefore, important to watch this carefully so that the importing country's interests are not adversely affected. It is also important to monitor and watch the prices of imported drugs coming from the principals of the importers.

3.2.4 Essential drugs: In the light of experience, both in the developed and developing countries, it is now generally accepted that the number of drugs considered essential for treating a large majority of the diseases is relatively small. According to the model list of essential drugs, which is prepared by the WHO and is periodically updated, this would be around 200. In order that maximum benefit is derived from the limited resources available in developing countries it would be in public interest to commit them for import, production, quality assurance and distribution of drugs to be used for handling diseases more commonly prevalent in the country. Another important consideration in formulating the health programmes around essential drugs is the fact that over 95% of these are old drugs whose patents have expired. These can, therefore, be manufactured in any country and/or procured from any source which is the cheapest.

It is, therefore, important for a country interested in using its resources optimally to identify its essential drugs. The list will vary from country to country depending upon its disease pattern, financial resources, domestic production facilities and related factors, and socio-political and techno-economic conditions, but some common measures could be :

- Public health services like social security and medical insurance schemes should accord primacy to essential drugs;
- Special incentives should be provided for the production of essential drugs;
- Public sector industry should be concerned mainly with the production of essential drugs;
- Imports, where necessary, should be restricted mainly to essential drugs;
- National Formulary should reflect preference for essential drugs;
- Discussion and promotion of this concept in pharmacy and medical schools
- Regular review and updation of the list of essential drugs by a standing committee or other suitable mechanism.

3.2.5 Traditional system medicines: In a number of developing countries a large proportion of the population uses drugs of the traditional systems, some preforce because of the non-availability of modern drugs but many because of their faith in them. These drugs form a part of the socio-cultural milieu particularly of the old world countries. These drugs do form an important national resource which should be utilized in a well-planned manner. As these are produced from local raw material their usage would provide economic benefits to the population. Many of these would be cheaper than modern drugs and would provide economy in drug prescribing. Their use would save foreign exchange in countries dependent on imports. However, certain steps would need to be taken to rationalise the traditional system drugs. These should include the following:

- Determination of rational position of traditional system drugs in the light of contemporary developments in therapeutics for medicare programmes.
- Modernisation of production techniques for traditional system drugs.
- Inclusion of traditional system drugs in community health and primary health centre kits.
- Carrying out intensive R&D on the traditional system remedies for making fuller use of this valuable resources including development of new drugs.

4. PHARMACEUTICAL INDUSTRY AT REGIONAL LEVEL

- 4.1. **Indian experience:** As drugs are one of the essential needs of society, for economic and strategic reasons it is important that the imbalance in respect of production and consumption of pharmaceuticals, to which reference has been made earlier, should get rectified as early as possible. It is not only of interest to Third World countries but also of benefit to the developed countries because such imbalances are a cause for political and economic frictions. As the pharmaceutical industry in developing countries is not in a state of uniform development, the strategies to be adopted in this regard have to be suitably altered to meet the requirements of the given situation. The national industry in countries like India is capable of meeting most of its requirements of dosage forms. It has also developed capacity for manufacture of a number of drug substances and the country is on its way to becoming essentially self-reliant.
- 4.2. **Growth of industry in India:** The Indian experience in operating its drug policy and development of the pharmaceutical industry over the years has been rewarding and educative. The development of the pharmaceutical industry had been accorded special attention by the Government of India in its industrial policies and plans since independence. The pharmaceutical sector policies essentially originate from India's Industrial Policy (1948, 1956, 1973, 1981), Science Policy (1958) and Technology Policy (1983) resolutions and statements. The Hathi Committee Report (1975) was an important event in the history of the pharmaceutical industry. The statutes which have a direct bearing in regulating the overall growth and development of the pharmaceutical industry are the Essential Commodities Act (1955), the Companies Act

(1956), the Patents Act (1970), and the Foreign Exchange Regulations Act (1973). Some other supporting statutes directed specially to the pharmaceutical industry are: Drugs & Cosmetics Act (1940), Pharmacy Act (1948), Drug Policy (1978, 1986), Drug Prices Control Order (1970, 1979, 1987). Health Policy (1983) and Drug Policy Measures (1986). Consequently, the pharmaceutical industry has made impressive progress over the years, as shown by Table III. What is more significant is that the industry has been able to establish a self-reliant technology base, and is able to manufacture most of the requirements of drug substances, including those introduced abroad in the last few years.

Table III. Growth of pharmaceutical industry in India.

Year	Capital Investment in Pharm. Industry*	Production	
		Drug Substances	Dosage forms
1952	24	10	100
1964-65	66	17	135
1975-76	300	130	560
1985-86	700	409	1945
1989-90 (estimated)	900	575	3225

*The figures are in Indian Rupees in crores; Rs. 1 crore = US\$ 0.6 million (approx.).

4.3. **Important elements of drug policy:** The salient features of the drug policy in India have been:

- Assignment of well-defined and regulated roles to both public and private sectors of the pharmaceutical industry with emphasis towards channelisation of the activities of foreign companies, promotion of the Indian sector and provision of significant role to the public sector.
- Use of a system of registration and licensing to regulate the import, manufacture, sale and distribution of drugs. The growth of the Industry is directed towards indigenous production of essential drug substances and dosage forms and establishment of a self-reliant technology base.
- Special registration provisions for drugs of the traditional systems. Recognition of the traditional system for the national medical and health services.

- Provision of special incentives for in-house R&D and indigenous development of technology.
- Selective price control, particularly of essential drugs, with fixed mark-up on the costs, and overall fixed profitability control.
- Special provisions in patent laws for drugs (and for all chemical process-based industries) allowing only process patents, seven years for life of the patent from the date of filing or five years from the date of acceptance and liberal provisions for compulsory licencing and for licence of right.
- Phased backward integration to production from basic stages and linking of formulation capacity to production of drug substances.

4.4. **Characteristics & Structure:** The more significant characteristics of the industry are:

- Practically all dosage forms are indigenously manufactured;
- Near self-sufficiency in capability for production of drug substances including those recently introduced in modern medicine.
- Rising exports with many units recognised/registered for exports to developed countries in Europe and the U.S.A.
- Modernised production of traditional system drugs and widespread use of such drugs by even physicians of the modern system particularly for conditions for which modern drugs are inadequate as e.g. liver disorders.

Broadly, the structure of the industry at present is as follows:

- About 200 units in the organised sector including 5 public sector companies, which are Government owned and managed, and 45 private companies, which are associates of multinational companies with foreign equity ranging from 40-75%, and the rest are Indian companies in the private sector.
- Around 10,000 medium or small scale companies with a capital of less than Rs. 100 lacs engaged in production of both drug substances and/or dosage forms.

- A good inhouse process technology development base established in the industry so that the lag time for developing alternative commercially viable processes for drugs introduced abroad has been considerably shortened.

4.5. **Regional cooperation:** Other countries like Sri Lanka and Bangladesh of the Indian subcontinent have been taking steps towards gradual indigenisation of their requirements. In the present situation, it may be more practical and advantageous if regional cooperation in drug production could be organised so that countries of a particular region, like say for example the SAARC countries, could pool their resources and meet their requirements by mutual assistance. Countries with the least developments in the pharmaceutical field can initiate action for packaging and production of dosage forms and later follow up with manufacture of drug substances and chemical intermediates as well as of ancillaries and packaging materials. All these stages of production need not be started simultaneously. One can stagger them to suit the given situation and resources.

5.0. PHARMACEUTICAL INDUSTRY DATA BASE AND INFORMATION CENTRE

5.1. **Background:** The pharmaceutical industry is a multi-disciplinary endeavour. The industry dealing with manufacture of dosage forms and their packaging as well as production of biologicals and biotechnology-based products requires expertise from and interaction between pharmacists, chemists, engineers and biologists. The manufacture of drug substances is basically an extension of the fine chemicals and chemical intermediates industry and requires interaction between chemists, process and chemical technologists and engineers. R&D work for new drug development requires very close interdisciplinary approach by scientists from a number of disciplines. For computing plant capacities, a great deal of information is needed from public health scientists, economists, marketing people and social scientists. Post-marketing monitoring requires inputs from marketing groups, clinicians, and clinical pharmacologists. For the efficient working of all these groups a great deal of highly specialised information and knowledge is required. These groups would also generate a large amount of data and information which would need to be collated, analysed and disseminated. This has become a specialised area and is best done by a fully automated Information and Documentation Centre. The various functions which this centre should perform are described below.

5.2. **Quantification of drug requirements:** While the actual consumption of drugs in a country can be fairly well computed by adding imports to local production and subtracting exports, this does not reflect the desired needs of a country. It would be desirable during planning for the future to work out estimates of the desired quantities of drugs needed so that one knows the gap between the actual consumption and the desired needs before proper planning for catering towards filling this gap can be made through increased production and imports. Two main approaches have been made for computing such requirements:

5.2.1. **Health data based estimates:** In this approach, the assumption is that the requirement is dependant on the disease pattern and the buying capacity of the population. Information is, therefore, needed on the following points:

- Public health statistics, morbidity and mortality due to major diseases and related epidemiological trends.
- Population and its growth rate.
- Per capita income, buying capacity and trends of change.
- Infrastructure available for health care, including hospitals, referral system, health delivery and drug supply systems.
- Data of drug consumption in hospitals.

Based on this data, mathematical models are developed to computer the requirements. It is, therefore, important to develop a system by which data on these parameters is continuously generated and fed into a data-base, where it is analysed to monitor the consumption pattern and forecast the future requirements, which would help in drawing up perspective plans.

5.2.2. **Consumption pattern analysis:** In situations where health requirements are not easy to ascertain it is convenient to collect past data of consumption over a number of years. Using this data, a regression can be calculated to compute the likely future needs. This method of need-forecasting is an easy tool to use as a guideline for future requirements but not with a high degree of accuracy.

- 5.2.3. **Relative advantages and limitations:** Consumption-based forecast of drug requirements gives basically an economic picture of the future needs, based on the market-supply-and-demand principle which reflects basically the average growth rate of the market and buying capacity of the population. The health-based forecasting, however, provides the correct picture of the real drug needs. The ideal would be to use both approaches; the difference between the two would reflect the inability of the weaker sections of the society to buy the drugs they need and provide a useful indicator for the gap to be filled to meet the health requirement. The public sector would need to focus its attention on this gap.

In countries where not much data is available for consumption-based analysis one could depend upon the pattern of consumption of one of the relatively more advanced countries of the region because the disease pattern of countries in a region is somewhat similar and would respond to similar drug usage.

- 5.3. **Update on recent developments:** There is need to constantly provide information on the recent developments in different fields of science and technology relevant to the pharmaceutical industry. This could be done by carrying out in-depth literature surveys, analysing and compiling this information in the form of regular bulletins and circulating them widely by the proposed Centre. An illustrative list of various fields which the bulletins could cover are given below:

- New drugs, vaccines and methods of treatment (including new delivery forms of drugs).
- Recent developments in biotechnology.
- Adverse drug reactions.
- New developments in pharmaceutical technology.
- Patent literature survey for pharmaceuticals and drugs.
- Business and policy issues.

- 5.4. **Data bank:** This Centre should maintain an updated directory of:

- Pharmaceutical industry units and their production data.

- Pharmaceutical machinery manufacturers and their production data.
- Pharmaceutical instrument manufacturers and their production data.
- Manufacturers of pharmaceutical packaging materials and auxiliaries and their production data.
- Manufacturers of intermediates required by the pharmaceutical industry and their production data.
- Technologies available for transfer.
- Project profiles and reports.

The Directory should be periodically updated and published for sale and distribution to those interested.

5.5 Bibliographic surveys: The Centre should undertake selective surveys on payment, which may include patent search, and specific technology queries (pertaining to pharmaceuticals, drugs and other special items falling within its range.

5.6 National Information Centre for Drugs and Pharmaceuticals (NICDAP): In India, a National Information Centre for Drugs and Pharmaceuticals (NICDAP) supported by the Dept of Science and Technology of the Government of India has been in existence since 1977. This serves many of the functions listed above for an information centre. This has recently been recognised by WHO as a collaborating centre for Drug Information for the South-East Asian Region comprising 11 countries which include Bangladesh, Bhutan, India, Indonesia, Democratic Peoples' Republic of Korea, Maldives, Mongolia, Myanmar, Nepal, Sri Lanka and Thailand. The main terms of reference of this Centre are:

- to develop and maintain an information base on sources of drugs (including medicinal plant substances) and dosage forms, prices, terms of registration, and patent status, particularly within South-East Asia;
- Maintenance and updating of comprehensive scientific data on drugs, to support requests for bibliographic information from member States; and
- to train personnel from member countries in the organisation of the drug information system.

The Centre will provide information on availability of raw materials required for formulation of essential drugs and on their international prices, production technology of some of the essential drugs, therapeutic information on essential drugs, patent laws for new drugs, registration of drugs in the countries of South-East Asia, and training of nationals in the drug information system.

- 5.7. **Regional information centre for drugs and pharmaceuticals:** The pharmaceutical industry is one of the sectors, which offers the best prospects for cooperation among developing countries, specially of a region, as they have similar disease pattern. Quite often they have similar status of techno-economic problems and thus commonality of logistic problems. Thus the experience of one would be applicable to the others to a large extent. Cooperation could cover many areas from joint purchase and distribution to sharing of production of pharmaceuticals, joint research and development efforts directed to specific diseases requiring priority attention by the countries of the region. A joint information centre catering to the needs of countries of the region with joint human resource development and training programmes can be a boon to the countries involved. The most valuable and easy way to operate this would be to set up a Regional Information Centre for Drugs and Pharmaceuticals. Its main terms of reference could be similar to those of the NICDAP. In addition it may also get involved in collection and dissemination of information related to Human Resource Development facilities in countries of the region. It can provide training courses for scientists and technologists in areas like Information Sciences, Management Techniques, Quality Assurance Systems, etc.

NICDAP at Lucknow, could possibly be used by UNIDO also, like the WHO, as the Regional Information Centre.

- 5.8 **Regional Training Centre(s) for Human Resource Development:** Pharmaceutical production needs a wide range of expertise which includes management experts, pharmacists, pharmaceutical technologists, chemical technologists, quality control personnel, pharmacologists and others. The inadequate availability of trained scientists is very often a limiting factor in establishing production facilities. Many developing countries are too small to have their own training facilities in every field. The training received in the developed countries is very often not relevant to the situation in the developing countries. Besides, such training is very expensive when cost of living in the developing countries is taken into account. South-South regional cooperation for this purpose could be most useful. Special

arrangements could be made for sharing training facilities between different countries of a region. Special regional technology institutes, run with jointly administered governing bodies could be established for training at different levels; some of these institutes could be Post-Graduate Institutes established under the aegis of UNIDO. It is proposed that UNIDO may consider establishing an Asian Post-Graduate Institute of Pharmaceutical Sciences in this region dedicated to the special pharmaceutical technology needs for countries of this region.

6.0. SUMMARY AND CONCLUSIONS:

After discussing the background of the pharmaceutical industry with particular reference to the situation prevailing in developing countries, an attempt has been made to highlight the need for developing systems for collection and dissemination of relevant information. Setting up regional Information Centres could greatly assist in the growth and development of the pharmaceutical sector in countries of the region. The main objectives of these Centres should be to provide:

- Comprehensive and updated information about the sources of supply and prices of drug substances and their dosage forms both from within the region and outside;
- Information on manufacturers of pharmaceuticals, machinery and auxilliary materials of each constituent country;
- Information on raw materials including medicinal plants and packaging materials available in each country;
- Information about new drugs, drug-drug interactions and adverse effects of drugs;
- Bibliographic surveys;
- Training courses particularly for scientists and management personnel from Third World countries.

As a National Information Centre for Drugs & Pharmaceuticals, which is already acting as a Collaborating Centre of the WHO, is already available in Lucknow, this nucleus could be considered as a candidate for the Regional Centre under the aegis of the UNIDO.

Training personnel for the pharmaceutical sector is an important necessity, specially for developing countries.

It needs multi-disciplinary team work for achieving excellence and nurturing it. There is dearth of talent but the gap can be filled by pooling the resources of a region. The setting up of a Regional Institute for Pharmaceutical Sciences for South Asia or South-East Asia with emphasis on the particular needs and demands of the region may be given serious consideration. Outstanding pharmaceutical scientists, technologists and allied personnel can be attracted to such an institute to work on the faculty so that personnel required for different branches of the pharmaceutical sector are available to the countries of the concerned region.