Chapter 7

Conclusions, Findings
&
Observations
THE PRESENT SITUATION

The grossly unequal distribution of drugs between developed and developing countries has not changed much in the past decade. In 1985 75% of the world's population still accounted for less than a quarter of total drug consumption, and between 1.3 and 2.5 billion people had little or no regular access to the most essential drugs. This uneven distribution of drug consumption is associated with uneven distribution of drug production, which is still concentrated in a few developed countries. As in the past, large multinational companies play a key role in production and trade, and pharmaceutical innovation continues to make an important contribution to health. Nevertheless, throughout the world, but mainly in the developing countries, there are diseases for which the treatment is inadequate, and new drugs are urgently needed. However, more detailed investigation of this grim picture shows that important changes, which are not always discernible in the global figures, have occurred at both the international and the country level.

The past 10-15 years have witnessed a major debate on the question of drugs, a debate kindled by, inter alia, the vast number of drugs on the market, increased awareness of the potency of drugs, the cost of drug treatment, the potential for developing new drugs, and the undermedication or overmedication of large segments of the world's population. Increasing attention has been paid by governments to developing mechanisms to improve the availability and rational use of drugs. With the growing awareness of the need for a national drug policy as part of a national health policy, many developed and developing countries, for different reasons, have tried to rationalize their drug sector. Some have drawn up limited lists for general practitioners. Others have embarked on national essential drugs programmes to make
better use of the scarce resources available. Although some developing countries have been slow in implementing essential drugs programmes, none has rejected the concept and nearly all have a list of essential drugs under their generic names. It can be assumed that the coverage of the population with essential drugs has increased in the past five years. Consumers have also played an important role in advocating the provision of more and better drug information to the public and in supporting the creation and aims of a national drug policy. The academic world has also been concerned about the irrational use of drugs and has promoted more intensively improvements in the prescribing practices of health practitioners. The concept of rational drug use is gaining greater support and appears on the agenda of most meetings dealing with public health.

Nevertheless, it is evident from this report that the situation still gives cause for concern. Few, if any, countries have attained the objectives of making effective and safe low cost drugs available to the entire population, ensuring that they are used rationally, and developing technically and financially sound national production of drugs in support of the economic growth and overall development strategy of the country.

Although the situation in individual countries varies enormously, some general conclusions can be drawn about the problems and constraints and the opportunities created by new developments at the international and national level.

**National drug policies:**

It is clear that the first requirement in developing a national drug policy is political commitment. If this commitment is lacking, a rational policy cannot be formulated or, above all, implemented. However, this report has shown that, even when commitment is present, there are many obstacles to the implementation of a
national drug policy. Essential drugs policies and programmes have been adopted by more than 40 countries with the objective of making the needed drugs available to the public sector in the right quantities and at affordable prices. In many developed countries, steps have been taken to rationalize the national drug policy. But internal and external pressures, the lack of resources, of a proper infrastructure, and of the manpower required, weakness of the ministries of health, absence of management and planning ability, and the economic crisis all slow down progress. The economic crisis has exacerbated the problem of providing essential drugs by on the one hand decreasing the resources available and on the other increasing the health and other problems of the population.

In some countries the economic crisis has been seen as an opportunity to rationalize the entire system from the importation to the utilization of drugs in order to save money. Moreover, all those concerned - the government, the pharmaceutical industry, consumer groups, health professionals, and the general public - are aware that the use of drugs needs to be, and can be, improved. This awareness is enhanced by the experience gained over the past five years in many countries, and explains the interest of bilateral and multilateral agencies in essential drugs programmes.

It can be expected that in the future yet more countries will develop their own drug programmes and policies and increased attention will be given to the long-term sustainability of the programmes by the countries themselves, the donor community, and the international organizations through, inter alia, cost-recovery schemes and ways and means of obtaining hard currencies. There is also a growing trend for governments in most countries to take an active part in determining the way providers of pharmaceuticals should operate, using a wide range of approaches to develop policies and regulations that benefit the majority of the population. They continue to
be opposed by groups with different interests represented in or influencing
governments, which lobby against changes that may harm their position. Having
raised the alarm in previous years, consumer groups continue to promote public
access to more and better information about products, greater availability of drugs for
the poorest members of the population and lower prices.

Double standards in the marketing and promotion of drugs in developing
countries have been the subject of wide debate in recent years. WHO has developed
ethical criteria for medicinal drug promotion that could be adapted by governments
and used by all those concerned. Independent observers have noted an improvement
since the introduction of a voluntary code of marketing practices by the International
Federation of Pharmaceutical Manufacturers Association (IFPMA). The general trend
in dealing with these very sensitive issues is towards responsible co-operation rather
than confrontation. The outcome of these conflicts and negotiations will, together
with political commitment and investment of resources, determine the capacity of
countries to attain their health goals.

Drug regulatory authorities:

While there is a long tradition of pharmaceutical regulation in developed
countries, the past decade has been characterized by the strengthening of adverse drug
reactions, and the development of post-marketing surveillance. Efforts have also
been made to speed up the registration process. Opinions about the future of
regulation in developed countries differ. Some think that it will not be very different
from what it is today; safety and efficacy will continue to be prerequisites to
registration. Others believe that developments in the electronic exchange of
information, greater acceptance of data from other countries, standardized formats for clinical and preclinical studies, and the need for speedier product registration will increase the pressure on regulatory agencies and lead eventually to their world-wide standardization. In developing countries, although only a few drug regulatory authorities are fully functioning, there is a trend towards developing small but effective drug regulatory authorities. In this context the availability of information is crucial. In the past few years, WHO has considerably increased the dissemination of validated information, thus enabling governments to take more rational decisions.

Drug procurement and availability:

The same constraints as operate in developing countries in the implementation of a national drug policy operate in attempts to improve the availability of essential drugs. The lack of foreign exchange, the absence of a rational system of procurement with a good selection and quantification of the drugs needed, and the difficulty in obtaining information on suppliers and on prices of finished goods and raw materials are additional problems. However, a large number of countries have achieved some progress in this field by taking advantage of the wide availability of generic drugs at low cost on the international market, regional cooperation, cost recovery schemes, guidelines for the selection and quantification of drugs, and the services offered by the supply division of UNICEF(UNIPAC) and other non-profit organizations (e.g., IDA, ECHO). As long as rationalization applies to the public sector only, the opposition is not too strong; but the situation is different when it is applied to the private sector, as seen in Bangladesh. Success in the years to come will depend on the capacity of health systems in a period of economic crisis to create efficient, fair, flexible sources of finance ensuring the sustainability of the drug policies and programmes.
In developed countries cost-containment measures in the health sector will no doubt continue. A consequence will be promotion of investment in the production of drugs that will decrease hospitalization, the development of formularies at hospital level and, in some countries, the establishment of limited lists of drugs.

It is forecasted that, by the year 2000, the pharmaceutical market in both developed and developing countries will have increased to at least US$ 200 billion. It is also expected that the current trend towards internationalization of sales and research and development will continue, as well as the tendency to mergers, with the bigger pharmaceutical companies acquiring the smaller ones. Only a few biotechnology firms will have enough capital to develop, register, and market their own products. The generic market, generic prescribing, and drug substitution may also be expected to increase as a result of population increases, efforts to improve the health care coverage in developing countries, and pressures on prices in developed countries. These pressures may also have an impact on research efforts.

Research:

Drugs that will be on the market by the 1990s have already been developed; thus current research is on drugs that may be expected to appear in the late 1990s. The five leading categories are expected to be: cardiovascular drugs, antibiotics, psychotherapeutic products, antispasmodics, and drugs to combat cancer. However, the spread of acquired immunodeficiency syndrome (AIDS) will lead many companies to step up research on antiviral products. The effect of AIDS has already been seen on the stock market, with sharp rises in the share prices of companies considered to have a potentially effective treatment.

The emergence of biotechnology could dramatically reverse the decrease in research and development output alleged to have taken place in recent years. The
development of monoclonal antibodies, recombinant DNA, genetic engineering, and
receptor identification seems likely to have a profound effect on the future of the
pharmaceutical industry. The challenge for the biotechnology companies in the next
years lies in the commercialization of their products, the financing of their enterprise,
reasonable patent protection, and the affordability of their products.

The aging of the population in developed countries is also likely to have
important repercussions on the pharmaceutical market and on research. New kinds of
drugs will be needed to enhance memory and to treat chronic and degenerative
diseases, as well as new drug delivery systems. Ways will have to be developed to
courage investment in the research and development of orphan drugs, i.e., drugs to
combat diseases that do not affect larger numbers of people. Diseases that affect
large segments of the population in developing countries will probably benefit
indirectly from these developments. Discussions will continue on how to reconcile
the need to encourage research on unsolved health problems with the need to make
medicines available at reasonable cost to society.

Production:

Some of the larger developing countries have maturing pharmaceutical
industries producing bulk materials and finished products covering most domestic
needs and increasingly including exports. Many larger countries are nearly self-
sufficient in the production of finished drugs but almost completely dependent on
imports of bulk raw materials. Many of the least developed countries have a few
formulation plants. These plants, with notable exceptions, have been largely
unsuccessful in producing drugs at an internationally competitive price; without
supporting industries or trained staff, and with difficulty in securing a position in the
local market, many operate at low capacity and the added value from the local production of generic drugs is low.

The larger middle income countries are likely to move towards increased self-reliance at an acceptable cost. It is quite likely that some of the maturing industries will develop innovative drugs as a result of increased investment in research and development. Many smaller countries will need to find internal or external support for the rehabilitation or modernization of their existing formulation plants; otherwise they will be forced to continue subsidizing inefficient production.

Judging from present trends, however, the developing world’s share of pharmaceutical production is likely to remain small, although an increasing number of developing countries will manufacture drugs as part of their overall development strategy, to keep costs low and save hard currency. How far they will succeed will depend greatly on the size of the market, their competitiveness, their willingness to seek the technology they need and the conditions of its transfer, local ability to adapt and develop technology, and the commitment of governments to their support. It will be a challenge for those countries to reconcile economic and health goals in the production of drugs and to ensure the production of low cost good quality essential drugs.

Some developments in the past few years have created, and will probably continue to create, new opportunities for local production. The patents of a number of products have expired and those of some of the top products in the world market will expire before 1990; there is wider acceptance of generics among the public; technology is increasingly available; market intelligence on raw materials has improved in developing countries; regional cooperation is developing.
It may be expected that the international pharmaceutical industry will try to maintain its position as a producer of drugs in, and exporter of drugs to, developing countries. The question of patents will continue to be debated, and the broader economic and political situation will determine the capacity of developing countries to formulate and manage their own drug policy. International organizations such as UNCTAD, UNIDO, and Who are taking an increasing part in providing technical support and information to developing countries.

Use of drugs:

The procurement or production and distribution of drugs require resources, knowledge, and skills but are fairly mechanical processes that do not call for changes in behaviour. This is not so for the use of drugs, which is a much more complex issue; no country, even the most developed, has totally succeeded in improving the prescribing patterns of medical personnel or the use of drugs by the public. Many obstacles exist to the rational use of drugs, ranging from lack of objective information and of continuing education and training in pharmacology to the methods of promotion employed by the pharmaceutical industry, the shortage of well organized drug regulatory authorities, the presence of large number of drugs on the market, excessive demand by the patient, the prevalent belief that “every ill has a pill”, and the attitudes of members of the medical profession, who only too often are reluctant to change their practices and view any restriction as a threat to the doctor’s freedom to prescribe.

Governments, however, often for cost-containment reasons, have become more aware of the problems linked with irrational consumption and polypharmacy. Some sectors in the academic world have also become conscious of the dangers of insufficient training in pharmacology. Hospital drug committees have been set up,
and independent publications discuss the rational use of drugs, including the role of
the pharmacist and the ways of increasing it. Consumers are being sensitized to the
issue by such publications and by the media. All these new developments present
opportunities for improving the situation.

Nevertheless, much more remains to be done. Increased self-medication will
require more and better education of both the public and health professionals so as to
avoid irrational use of drugs. The danger of drug interactions may also increase and it
is expected that adverse reactions will be under reported since use of over the counter
drugs may not be reported to or recorded by the doctor. Monitoring of product safety
for over the counter drugs will probably have to be improved at the level of the
pharmacies.

Success in achieving rational use of drugs in the future will depend to a large
extent on the ability of governments, WHO, the academic world, health practitioners,
the pharmaceutical industry, and consumers to develop information strategies and
generate ideas on the most effective role of drugs in society and within the health
sector. Given the increased awareness of the problems linked with the use of drugs,
current efforts to improve and disseminate the information available, to train health
personnel more efficiently, and to educate the public will be intensified. It is certain,
however, that the rational use of drugs remains a challenge.

Finally, the essential drugs concept has become increasingly accepted,
particularly for the public sector in developing countries. Is appropriate application
throughout the world remains a challenge for the future.

The overall situation:

Of the 5 billion people in the world, between 1.3 and 2.5 billion have little or
no regular access to essential drugs. These figures are based on the facts that, in 23%
of the developing countries reviewed, less than 30% of the countries, between 30% and 60% of the population have access to essential drugs; and in 45% of countries, 60-90% have access. The needs of most of the 1.2 billion people living in developed countries are mostly fulfilled.

Table...... Distribution of 104 developing countries according to selected indicators:

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<th>Level</th>
<th>Policy (%)</th>
<th>Legislation (%)</th>
<th>Essential drugs list (%)</th>
<th>Procurement (%)</th>
<th>Distribution (%)</th>
<th>Coverage (%)</th>
<th>Quality assurance (%)</th>
<th>Information (%)</th>
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Source: WHO secretariat.

The difference in coverage between countries is largely related to their financial situation, but this does not always provide a sufficient explanation. Policies and their implementation vary from one country to another, giving rise to a wide variety of situations. For example, 25% of countries have a well defined national drug policy, 41% are currently developing a policy aiming at a better availability of essential drugs and 29% are either considering implementing some kind of essential drugs policy or have no interest in such a policy.
Although many of the 104 countries show an apparent lack of willingness to adopt a strong and effective drug policy, a majority have drug legislation as well as an essential drug list. Over 65% have legislation that has been classified at level 2 or 3 i.e., they have a drug regulatory administration but it is not fully functioning. Nearly 90% have a revised essential drugs list by generic name at level 2 or 3. However, as will be seen in more detail in the following chapters, many countries do not have the capacity to enforce legislation and/or essential drug lists.

As regards the procurement and distribution of drugs, the situation is more clear cut; about 80% of the countries have been classified under level 1 or 2, which means that only a minority have a proper system of procurement and distribution. This result is not unexpected in view of the limited infrastructure in many developing countries, their lack of experience in the field of international procurement, and the weakness of their situation on the international scene. This makes it all the more remarkable that despite the unfavourable environment, 20% of developing countries have a functioning and adequate procurement and distribution system.

Quality control exists in most countries. More than 70% of the 104 countries have some mechanisms for assessing the quality of products or have a quality control laboratory. However, in many of them, this control does not function effectively.

The rational use of drugs remains an area where progress is needed. There is no good system for providing objective information. In most countries, adverse reactions are not monitored and continuing education is not carried out systematically (94% of the countries are at level 1 for this indicator). For many of the Third World countries, the main issue is still how to improve the availability of essential drugs; rational use does not appear to many governments to be a priority.

How Safe are our medicines:
Two resolutions in Europe are regarding drugs went almost unnoticed recently.

In the United Kingdom, the Medicines Information Bill - a bill ...to provide greater access to information on drug safety and effectiveness, and to reasons behind regulatory decisions - was introduced by Member of Parliament Giles Radice.

In Switzerland, members of Health Action International - an organisation campaigning for greater openness in drug control among various national regulatory agencies, physicians, pharmaceutical associations and consumer organisations - unanimously resolved to persuade their respective governments and the European community for greater public access to drug information.

HAI, a network of over 150 consumer, health and development organisations in 60 countries, is trying to make information about drugs more easily accessible to consumers. HAI officials stress that only legitimate trade information relating to the manufacturing progress of individual pharmaceutical companies should be allowed to remain secret.

But in reality, much of the information regarding the chemical composition of medicines and their possible adverse reactions is kept away from consumers and in some cases even from the medical practitioners.

Take the case of the contraceptive Norplant. First marketed in Finland in 1989, and subsequently marketed and used in the South, women now suspect that it is not safe and has harmful side effects. A Finish researcher asked for permission to see the studies submitted for licensing of Norplant.

"I wanted to find out if sufficient studies on the side effects of Norplant had been conducted to allow extensive marketing all over the world," says Dr. Eeva Ollila. More than three years and numerous inquiries later, she finally received permission to view the documents.
Ollila points out, “It is theoretically possible to get this information, but after waiting endlessly”.

HAI Europe co-ordinator Catherine Hodgkin highlights another dimension of the problem - the different procedures of divulging information about drugs internationally. In Finland, access to drug registration information is possible with special permission, but it is a difficult procedure. In the U.K., the Committee on Safety of Medicines is legally protected from disclosing drug registration information or reasons for regulatory decisions.

However, such legal provisions sometimes prove embarrassing for the regulatory agencies and alarming to the consumers. An ideal example of such a case is that of Halcion (triazolam), a widely marketed sleeping pill produced by Upjohn. Very popular among women and the elderly. Halcion was suddenly withdrawn from the U.K market in October 1991, and its use severely restricted in many other countries.

“It was very disconcerting for Halcion users to suddenly learn that the drug which they had been using regularly was no longer considered safe, says Deborh Khudabux of the UK National Consumer Council.

“They were more alarmed when they could not find out the reason for the withdrawal of the drug from the market, she adds.

Ironically in the UK consumers and prescribers learned more about the health risks of Halcion from media reports in the US, where the freedom of information act allows this kind of disclosure and even permits litigation.

When forced to open their files in a US court case in 1991, Upjohn admitted that several side effects such as paranoia, depression and memory loss had not been reported earlier due to a “transcription …… …….analysis of the data included 453
reports of psychiatric side effects, rather than the 123, as originally reported by Upjohn.

The Halcion case highlighted the lacunae in drug regulation and drug related ethics under severe public scrutiny. But despite all this there is deep cynicism in the scientific community internationally towards access of information. DES action Netherland – a vol untary agency formed against the drugs DES ”In 1971 it was found that the drug caused various problems, including complications during pregnancy and a rare form of cancer in the men and women who were prenatally exposed to the drug. But it was only four years later that DES was contraindicated in Netherlands”.

If the regulatory authority had felt publicly accountable for their decision would they have waited so long to act?” asks Hoen.

DES (diethylstilboestrol), a synthetic form of the hormone estrogen, used to be widely prescribed for pregnant women during the 50s and 60s in many European countries, Hoen is one of victims of DES.

This misplaced caution in sharing information is however not felt by all regulatros of members of the pharmaceutical industry. At the UK Medicines Control Agencies annual meeting this year, Sir James Black, the winner of the 1988 Nobel prize for Medicine and Physiology stated “the main enemy in drug development is ignorance, and more openness is needed to over come it.”
PUBLIC IMAGE OF THE DRUGS INDUSTRY AND THE PHARMACIST IN INDIA

The Indian drugs industry has made great strides in recent years despite many of the contracts under which it has had to work. There was the difficulty in availability of raw materials as some of these were distributed and imported by the state trading corporation. There was no urgency in indicating some of these items as it was bureaucratic control. The manufacturers were also only allowed to sell formulations at an approved price under Drug Price Control Order (DPCO). These prices were unrealistic due to inflation. The revised prices became uneconomic. The machinery to approve revised prices was very slow and a very long time elapsed between the request for revision and the final approval of the new prices. Unrealistic limits were fixed for the quantities of formulations manufactured under licence and many manufacturers had to avail the services of loan licensees. Some of the difficulties have been solved to a great extent and yet the question of realistic prices for formulations continues to worry the manufacturer of drugs. Drug intermediates are subject to high customs duty and it has been found that it is cheaper to import a finished bulk drug make it from an intermediate.

Politician, government officials and the lay public are generally under the impression that the industry makes huge profits and is perhaps one of the most profitable fields of investments. The pharmaceutical industry is completely on an ancillary industries and while there is no control on ancillary industry, the pharmaceutical industry is expected to follow the price control regulations. The public image of the drugs industry as a whole is negative. Since the media have brown up some cases of rampart adulteration and spurious drugs, the public believes that except for few honest manufacturers the drugs industry composed of crooks and
racketeers. The true picture of the industry mostly honest producers with a few black sheep is not known. Despite the education programme carried on is newspapers by the industry organizations (OPPI, IDMA, PAMDAL) the public has not changed its image of the industry.

The public also has poor image of the pharmacists. Alongwith the industry a pharmacist is labelled as an unethical profiteer. The public blames the pharmacists for causing undue shortages of essential drugs. They state that these professionals hoard drugs and cause artificial shortages to make bumper profits. The public blames the pharmacists for encouraging adulterators and spurious drugs manufacturers. The public blames the pharmacist for substituting prescribed formulations (after without permission) and storing the formulation improperly. To increase the profit it is said that a retailer opens a big package and asses it to fill many prescriptions. All low of proper storage (cool, dry place or absence of moisture) are being violated.

The drug industry and the pharmacists have to accept the challenges of the consumer groups and satisfy them in a rational, scientific way.

THE DECLINING PROFITS:

The pharmaceutical industry claims that the profitability rates dipped to 4%. It is the industry estimated average of some selected small, medium and large units based on various national input and output costs. It is an alarming situation if the industry cannot improve upon the existing level of profitability. Apart from the replacement costs to be made good at the increasing inflated rates, the industry is expected to increase its R&D expenditure to sustain its leadership in producing qualitative products and to meet the increased awareness of G.M.P. standards.

With the advancement of science and technology in the present computer world, the updating or modernisation of the laboratories in the pharmaceutical
industry with the latest testing apparatus has made the industry as capital oriented. Thus the industry is in need of cash resources to invest in capital expenditure. In the recent news, some of the leading manufacturers have stopped producing unremunerative priced products and some have slowed down their production, with the result, the increasing trends in bulk drug and formulation production reversing and the market is experiencing dearth of essential drugs. The industry puts the blame on the DPCO 1987 which the Govt. implemented on its own accord without taking the industry into confidence.

The industry is made up of small, medium and large sized units, old and new, some enjoying monopoly while some are striving hard to live in fierce competition. So controlled through the pricing mechanism of the DPCO 1987 should aim at wider categorisation of the medicinal products with different profitability step up rates. It should also give differential treatment under different situations. So the concept of simplicity or simplification of the price fixing formula is not relevant to take care of 250 and odd medicinal products manufactured and marketed under the influence of different cost factors.

The bulk drugs produced lythessi units are too small to influence or to control the markets. Leaving them out of the control basket, would amount reducing the work load in the Govt. department so they can concentrate their efforts on other areas of price control which volume wise is larger and time consuming to bring in, the effective and meaningful control envisaged in the DPCO’s

The industry is expected the DPCO '87 would contain an automatic price adjustment formula to care of the increases in the input costs. It should be based on periodical review of the input costs. Such price variation formula are common in other industrial pricing order. Even the wholesale price index supposed to affect one
crore workmen employees dearness allowance in industrial sector is evolved on national input costs and is widely used in our country. But the DPCO '87 did not venture to introduce the price variation formula to increase or decrease the cost with the corresponding variations in input costs. With the result, the situation has come back to the original point of dispute.

Over and above, the implementation of DPCO '87, in particular revising the bulk drugs prices and fixing the conversion norms are considerably delayed. With the result, the industry has no other go but to bear the losses consequent to the stagnated selling prices in face of raising input costs.

The industry spends or is spending on short term and long term basis for Research and Development activities. The major benefits occurring through the Income Tax incentives are withdrawn and no more available to the industry. No alternative means in place of such discontinued benefits are evolved before they are removed. In fact the drug industry with research orientation needs a weighted consideration as a matter of incentive for the money spend out and the efforts put in for one time expenditure on inventing new products and new processes.
INDUSTRY SCENARIO

The Pharmaceutical Industry in India provides excellent facilities. It has quality producers and many units are approved by regulatory authorities in U.S.A. and U.K. It has a pool of personnel with high managerial and technical competence. Its track record of development, particularly in the area of improved cost-beneficial chemical synthesis for various drug molecules in excellent. In produces a wide variety of bulk drugs and exports sophisticated bulk drugs.

The Indian market has some unique advantages. India has a 49-year old democracy. It has an educated work force and English in commonly used. It has a solid legal framework and strong financial markets. Professional services are easily available. They're in already an established international industry and business community. The country is now committed to a free market economy and globalisation. Above all, it has a 200 million middle class market, which is continuously growing.

For the fist time in many years the international pharmaceutical industry is finding great opportunities in India. The process of consolidation that has become a generalised phenomenon in the world pharmaceutical industry has started taking place in India.

9th Five Year Plan (1997-2002)

For the preparation of the 9th Five-Year Plan (1997-2002) the Planning Commission constituted a Working Group on Drugs and Pharmaceuticals. The main terms of reference of the Working Group were to review the achievements of the Industry vis-a-vis the international scenario. The Group would also identify major variations, if any in the achievement of targets set for the 8th Five-Year Plan. It would
prepare estimates of the Demand, Production and Projections for the 9th Five-Year Plan period. Four Sub-Groups were constituted by the Government for Preparation of papers on (1) Demand, Export etc. (Sup-Group I): (2) Infrastructures Requirements, Pollution Control, Industrial Safety, Training and Development of Manpower. Etc. (Sub-Group II); (3) Research & Development, Technology, Matters related to post- GATT Scenario (Sub- Group III) and (4) Indian system of Medicines and homeopathy (Sub- Group IV)

The following Members represented OPPI and participated actively in the deliberations:

Sub-Group I : Demand, Export, Investment, etc.
Mr. M.V. Venkateswaran, Vice-Chairman,
Pricing & Taxation Committee

Sub-Group II : Infrastructure Requirements, Pollution Control, Industrial Safety, Training and Development of Manpower, etc.
Mr. Ajit Singh, Chairman,
Exports & Materials Management Committee

Sub-Group III : Research & Development, Technology and all matters related to Post – GATT Scenario-
Dr. K. Kalyan, Chairman,
Research & Development Committee

The objective of the Sub-Group I on Demand, Export, Investment, etc., was to fix targets for 9th Five-Year Plan in terms of [i] Production, [ii] Exports, and [iii] Investment. It was noted that the forecast would depend upon the needs of the primary health centres and their estimated expenditure on medicines. The objective of the National Healthy Policy and allocation of funds in terms of this policy would be
one of the determinants in this context. Our Association assisted the Sub-Group in preparing the consumption data of 102 bulk drugs for the years 1993, 1994 and 1995.

It is estimated that by 2000 A.D., Industry's production will be around Rs. 35,000 crores out of which the bulk drug production will be around Rs. 7,000 crores. Exports will range between Rs. 8,000 crores to Rs. 10,000 crores. The investment expected in the Industry will be around Rs. 7,000 crores.

The Sup-Group II on Infrastructure Requirements was required to assess the infrastructure requirements like power, roads. Communication, requirements of equipments/machinery and indigenous capability for fabrication of equipments; steps necessary to mean pollution and safety control standards and assessment of the needs of employment, training & development and infrastructure. It was understood that for pollution Control, the World Bank had in 1991 given aid of Rs. 405 crores. The Chairman of the Sub-Group made a recommendation to the Planning Commission that 10% of this aid should be allocated to the Pharmaceutical Industry for Effluent Treatment; 50% of the cost may be borne by the Government (half by the Centre and half by States) and 50% by Industry through loans from Industrial Development needed for research during the post-GATT Period were worked out.

The sup-Group III on Research & Development and Technology assessed R&D status of the Drugs & Pharmaceutical Industry and studied 'Industry-Institution' linkage and investment in R&D both by the Industry and the Government in the context of the international scenario. Measures were suggested to strengthen the R&D of the Industry. The Industry could intensify its research activities if suitable amendments to the Patents Act are made as per the TRIPs Agreement and the Industry is allowed to generate enough cash surplus for ploughing back into Basic
Research for which the Industry has the necessary capability capability. The cash surplus can be generated only through removal of individual product price control.

Some of the important suggestions which emerged are as below:

❖ For basic R&D facilities, a company should create a total infrastructure so as to be able to undertake the complete work of a drug discovery.

❖ Recurring investment made by a company should be at least 50% of the turnover per year in the initial years.

❖ Companies who fulfill these criteria should be completely exempted from Drugs (Prices Control) Order (DPCO), for their entire operation in India.

❖ 200% weightage deduction on R & D expenditure on capital account under income-tax act should be given.

❖ Interest free or concessional loans for R&D capital expenditure, repayable over 10 th 12 years, should be given.

❖ Similar facilities as provided to publically R&D organisations and non-profit organisations should be provided to private sector in terms in terms of the Pass Book system.

❖ Green channel should be extended for customs clearance and complete Customs Duty exemption be given on R&D equipment, consumables such as, chemicals, bio-chemicals, etc.

**INDUSTRY EFFORTS**

"A National Specialisation Approach" and fast track for development of a few industries which have bright chances for success in achieving a place of distinction in the world market. He commended the excellent results of the South Korean experiment based on this model and suggested that the development of the Pharmaceutical Industry should be on such lines. The newly formed joint venture
alliances and increasing co-marketing arrangements are an indicator of the Industry's international recognition and vast potential. The President in his address also referred to the three main concerns of the consumer. They are in order of priority: availability and reasonable prices. He pointed out that the present pricing have unfortunately resulted in a gradual shift of production from price-controlled to decontrolled category; decreased availability of the cheaper molecules for the treatment of diseases under the National Health Programmes increased use of the more expensive broad spectrum antibiotics and proliferation of sup-standard drugs. He advocated a policy shift from control to regulation and development.

In his keynote Address, Dr. R.A. Mashelkar, Director-General of the Council of Scientific & Industrial Research (CSIR), speaking on "R&D" in the Pharmaceutical Industry – the Indian Challenge in the Global Context", listed as India's strengths, the pool of trained manpower which was readily available, the entrepreneurial qualities of its people and the great bio-diversity of the country. He explained the need for a better interface between Industry and research institutions.

The Industry's concerns were highlighted in various memoranda and presentations made to the Government. The President and his colleagues on the Executive Committee took several delegation to the policy-makers to explain the Industry's recommendations for a positive and growth-oriented policy. Comprehensive presentations were made at various dialogue meetings with Government authorities in Delhi and Mumbai.

ORGANISATION

EXECUTIVE COMMITTEE

As per Articles of Association, 18 Members were elected and 5 were co-opted on the Executive Committee. In addition, 13 Members were specially invited to all
the meetings of the Executive Committee. During the year 3 Members resigned from the Committee consequent to their new assignments.

Membership

The membership of the Organisation is now 74 (68 Ordinary and 6 Associate Member). One new Member joined the Association as an Ordinary Member.

Social Responsibilities

The Association, as a token of its consciousness towards its social responsibilities, took initiatives in contributing its mite to various causes of social welfare.

To commemorate the 50th Anniversary of the last march of the Azad Hind Fauj, the Azad Hind Expedition was organised to retrace the route taken by the Fauj from Singapore to India via Malaysia, Thailand and Burma. The members included INA veterans like Col. G.S. Dhillon and Col. Dr. Lakshmi Sahgal, and Mr. Sunil Dutt, Member of Parliament. The Expedition gifted medicines to a charitable hospital in Myanmar and also to another charitable rural health programme in Bangladesh. Member-Companies donated medicines for the purpose.

New Industrial Policy of the Government of Maharashtra

OPPI submitted a memorandum to the Satal Government containing its suggestions, especially regarding abolition of restrictions in the Government's location policy. These suggestions were also discussed at a meeting with Mr. V. Bansal, Industry Secretary.

Trade Marks

It was pointed out that when there in an infringement of a Company's Trade Mark and companies are forced to litigate to protect their Trade Marks, courts often do not award deterrent punishments. Companies should be more forceful in
demanding a stronger punishment and the Committee offered advice and assistance to Members to deal with cases of infringement of Trade Marks.

**Intellectual Property Rights**

Dr. Anil S. Mehta, President, made a presentation at a workshop on "Intellectual Property Rights- Its Implication for the Indian Economy" organised by The Associated Chambers of Commerce and Industry of India (ASSOCHAM). The gist of his presentation was.

- In the post – Gatt era, Indian Industry can no longer operate in a isolated economic system. In addition to capital and manpower, Knowledge or brainpower becomes a critical input. It is in this context that innovation have an added significance in today's business world.

- Because of our past history, unfortunately, discussions relating to IPR in the Indian democrat set – up get channelled along ideological lines. We must not however, forget that GATT – the General Agreement on Trade and Traffic – is all about trade and money.

- Adequate patent protection has always stimulated research and development. This is the experience of many Countries which have switched over from poor or nil protection to adequate patent protection.

- Italy amended its patent Law in 1978 and a comparison of the pre and post patent protection scenario in the case of that country's Pharmaceutical Industry is a real eye opener. The share of the market of the Italian pharmaceutical companies increased from 36% to 42% and R&D investment increased from 6.5% to 11% of turnover. Investment in the pharmaceutical Industry rose significantly and today Italy is the fifth largest producer of Pharmaceuticals in the world.
Similar was the case with Japan. After the introduction of Pharmaceutical product patents in 1976, there was a dramatic improvement in the health of the Pharmaceutical Industry in Japan. Over a 15-year time period, 1975 to 1990, R&D spending increased from 6% to 10.8% of sales and correspondingly Japan's share of original development of 'Major Global Drug's' rose from about 5% to 20%. Thus, today one out of five newly introduced Major Global Drugs is of Japanese origin.
Rajya Sabha Select Committee on Patents (Amendment) Bill 1995

The above Committee under the Chairmanship of Mr. V. Narayanaswamy met OPPI representatives. OPPI delegation consisted of Mr. D. Bhadury, Vice - President; Mr. K.S. Neelakandan, Vice - Chairman, Communications Committee; Mr. K.K. Master, Vice - Chairman, Industrial Policy & Legal Committee and Dr. (Mrs.) Richa Chandra, Member, Communications Committee. Submissions were made on the following points:

- India : Health Outlay – Declining Trend of Health Expenditure during the Plan Period (1st Plan to 8th Plan)
- Little known facts: "Comparison of the Pharmaceutical Industry with India's largest Private Sector Company"
- Third World Diseases Profile (Malaria. T.B. AIDS)
- Projected Demand for Drugs (NCAER Projections for 2,000 A.D. – Shortfall in Production)
- P&D Expenditure as % of sales in Indian Pharmaceutical Industry is 1.8% as against 16% in U.S.A.
- New Drug Approvals in U.S.A. (only 15-20 new drugs every year)
- World Bank Sponsored Study by International Finance Corporation on IPR. Foreign Direct Investment and Technology Transfer
- Roper Survey Results – An International Research Study on India regarding concerns of Foreign Investor)
- Italian Case Study: Patent Introduction leading to Growth
- Highlights of New Chinese Patent Laws
- Other countries experience introducing world class Patents Laws
Myth: "Prices of medicines will increase substantially by introduction of Product Patents" and The Facts

Myth: "IPR Implementation will drive Indian companies out of Business" and The Facts

Price Control

At a dialogue meeting in January 1996, with the Secretary, Department of Chemical & Petrochemicals and his colleagues, a comprehensive presentation was made suggesting that a fundamental change in the approach of the Government towards price control was urgently required. It was explained that the current span of price control along with its administrative mechanism is burdensome for the following reasons:

- Investment needed for growth is inhibited because of the uncertainty of administered pricing.

- Quality which is the hallmark of the Pharmaceutical Industry is not appropriately recognised and the standard are driven to a lowest common denominator level.

- Unremunerative prices create periodic and sometimes permanent shortages. Recent example are – Chloramphenicol, Vitamin C, Theophylline, etc.

- "Cost plus" prices are not linked to the value of drug therapy. As such, they cause distortions, sometimes harmful, in prescription practices.

The Pharmaceutical Industry in the only Industry which has been kept under price control for more than 30 years. It has a three-tier control, namely, product-wise control (bulk and formulations) and control on overall profitability. Such control are indeed outdated in an era of free market economy.
It is a national that full potential for the growth of this lifeline industry should be realised. The current production levels are far too short as compared to the demands – whether they are the MCAER projection of Rs. 16,000 crores or the 9th Five-Year Plan Estimates of Rs. 35,000 crores in 2000 A.D. Moreover, there is good scope for increasing the range of exports to at least Rs. 10,000 crores. Modern medicines reach hardly 30% of our population. Due to changing disease patterns our people require newer and better medicines. This calls for more investment in R&D activities. If this is to take place, the Industry does require a congenial environment which stimulated free growth and fresh investment. To achieve this objective, the following recommendations were made to the Government:

- There is need to re-examine the existing criteria for selecting drugs to be in price control as they do not adequately reflect the high degree of competition in the Indian market.
- The turnover criteria of Rs. 4 crores needs significant upward revision.
- The number of formulators (10) and market dominance should be determined by looking at therapeutic segments and not individual drugs singly.
- The number of bulk producers (5) in no longer relevant as drugs can be freely imported.
- Deleting 6 drugs from price control control each quarter on a trial basis.
- Adopting the alternative scheme of pricing as was successfully applied during the DPCO 1970 regime for 9 years.
- Allowing automatic adjustment of prices based on Consumer Price Index (CPI). The ultimate objective should be progressive decontrol and creation of conditions where the Industry regulator itself through market competition.
National Pharmaceutical pricing Authority (NPPA)

The much acclaimed scheme of the formation of a National Pharmaceutical Pricing Authority (NPPSA) has yet to see the light of the day. The Industry hopes that this new Authority adopts a fresh approach to the entire issue of pricing of drugs. This is possible only if the NPPA is headed by a person with vision who can give guidance and directions and not merely constrict and control prices. Adequate representation from the Industry will be essential in formulating policy and instilling a sense of partnership between the Government and the Industry.

Drug Price Equalisation Account (DPEA)

Drug Price Equalisation Account (DPEA) was set up essentially to encourage domestic production of bulk drugs through a system of retention pricing. However, in actual Practice, the operation of the DPEA gave rise to intractable administrative problems with anticipated accruals to the DPEA being thwarted by disputed and claims on the DPEA. The system therefore was correctly abandoned in the Rationalisation Measures announced in December 1986. Only recoveries of the past amounts "accrued" on account of actions taken under that Order were permitted under DPCO 1987.

Instead of simplifying the issues in a judicious and fair manner, the Government complicated the matter by dropping the phrase "actions taken under that Order" (i.e. those taken under DPCO 1995. The Industry Associations had strongly protested about this unwarranted provision at a dialogue meeting with the Government authorities. It was pointed out that, this modification purports to reinstate a defence power under an Order which has now ceased to exist. Despite repeated
assurances by the Government that it did not intend to use the provision against the Industry and wanted to retain its legal authority to recover only "accrued" demand, the Industry is now faced with a mounting number of totally fresh Notices. The Industry has repeatedly pointed out, in addition to the legal grounds relating to equity and fairness that these claim are not only unjust, unfair and one-sided, but they also operate as punishment on efficiency and prudence in purchases. If an overall view is taken they are counter-Productive and detrimental not only to the Industry but also to the consumer and the nation. Implementation and interpretation of DPEA provisions have been faulty on various grounds. Some of these grounds are listed below:

- Having implemented the price, as fixed by the Government from time to time, most of the claims are unsustainable.
- The need for set-off on account of sale at lower prices than notified prices as also on account of Government/Institutional sales.
- Adjustment on account of purchases of bulk drugs at higher prices than notified prices.
- Declining overall profitability of the Industry below the permitted level.
- Non-revision of prices of bulk drugs and formulations, at times for years, despite significant increase in costs of inputs and price applications.
- Non-consideration of purchases of other raw materials at higher prices.

The three-Member Committee appointed by the Government has not been able to give any relief of the Industry as yet regarding this irritant. As long as this Sword of Damocles hangs over Industry's head it is restricted from growing to its full potential.
Bureau of Industrial Costs & Prices (BICP)

At a special meeting organised in Mumbai, a detailed presentation was made to the Chairman and Member (Technical) of the BICP on July 11, 1996, in which the Industry's problems with the current pricing systems were explained. It was also stressed that there was a need for:

1. Greater transparency in price fixation;
2. Elimination of the unfair system of "actuals or norms" whichever is lower;
3. Recognition that the considerable time gap between making an application and granting a price works to the detriment of a manufacturer; particularly when prices are fixed for future time periods and especially when they are often out of date by the time they are announced.

It was suggested that there should be regular dialogue with Industry so that some of the long standing irritants could be eliminated by discussions and mutual agreement. The Industry appreciated the suggestion of the Chairman of the BICP that he would be prepared to allow higher prices to manufacturers who conform to superior standards of manufacture if these are certified by an independent body. [For example, WHO GMP certification.] It was agreed that this suggestion be pursued further.

EXPRESSIONS & MATERIALS MANAGEMENT

Material Management is a key function and concerns itself with improving performance in the major cost centre of a Pharmaceutical Company. With liberalisation, The Exports & Materials Management Committee found itself handling a lesser number of issues concerning Government Procedures, and was able to orient itself to developmental work and to focus on areas for professional improvement.
Additionally, the following issues concerning materials management and export development were identified, and remedial action initiated:

(i) Difficulties arising out of the operating procedure of handling import bills.

(ii) Counterfeit drugs being channeled in parallel trading.

(iii) Delay in testing of imported samples.

In a memorandum submitted to the Reserve Bank of India, the difficulties arising out of the RBI circular outlining operating procedures for handling import bills were explained. The difficulties primarily relate to routing the documents through Exporter’s bankers via Importer’s bankers. This procedure is both cumbersome and costly.

The issue of counterfeiting of drugs and parallel trading was taken up at a Session "Compliance Strategies for Counterfeiting and Health Trade" at the Symposium organised by the Drug Information Association (DIA). Philadelphia, U.S.A. in Mumbai in March 1996. The session was co – chaired by Mr. Ajit Singh, Chairman of the Exports & Materials Management Committee.

The delay testing of imported samples due to non functioning of the National Testing Laboratory at Mumbai was discussed at a dialogue meeting with the Drugs Controller General (India) The Joint Commissioner and Technical officials of the F.D.A Maharashtra were also present. The F.D.A. officials agreed to investigate as to how more samples can be sent for local testing. So that the results are available quicker and goods cleared speedily.

Efficient handling of the Materials function can in major performance improvement in an organisation. In order to enhance these managerial and supplier competencies, dialogue meetings with Managing Directors of well – known international pharmaceutical companies, as also Chiefs of Companies manufacturing
raw material/packing materials used in the Pharmaceutical Industry, were organised.
Mr. D.D. Chopra, Managing Director, Rhone-Poulenc (India) Ltd. in his presentation
spoke of contemporary in the materials function including 'Just In Time (JIT)
Inventory Planning Concepts and Forecasting' Mr. H.R. Khusrokhan, Managing
Director, Glaxo India Ltd., spoke on the complex role of the purchase and export
manager today as compared to yesteryear. This has necessitated in adopting many
new concept like supply chain management, Partnering with Suppliers’ Material
Requirement Planning, Just In Time (JIT) Inventory Management and using modern
Information Technology (IT).

Mr. Mukul S. Varma, Chief Executive of Indian Aluminium and his team of
Managers made a presentation on Foil & Packaging Business' relevant to the
Pharmaceutical Industry. Members made several suggestions concerning areas which
needed improvements. Mr. Uday Bhansali, a Senior Manager of Andersen Consulting
made a presentation on 'Materials Management and Strategic Cost Reduction'.

HUMAN RESOURCE DEVELOPMENT COMMITTEE

The Committee focused its attention on Training, Development, Motivation
and Commitment of Employees. This shift in priorities has been necessitated by the
fierce market competition and imperative needs to cement strengths of the
organisation for developing a proper synergy. In the changing business world, human
resources will play a significant part. A priority area for all progressive and forward-
looking organisations will be the development of Human Resources.

Job evaluation and reward management play a key role in organisational
development. Mr. N. Subramani, Regional Director of Hay Management Consultants.
Singapore, made a presentation on "Hay Approach to Reward Management".
Two residential workshops on “Managing Change and Creating a Pro-active Field Work Ethos” for the First line Managers of Member-Companies were conducted. The objective was sharpening awareness and understanding pro-active leadership behaviour and developing pro-active field work ethos through creativity, trust and mutual respect. Topics relating to Transactional Communications, Assertiveness, Performance Counselling, Practical Creativity and Achieving Excellence, Leadership and Team Building were discussed in depth. Video films, indoor and outdoor management games were used effectively.

A presentation on the “Role of Industry Associations” was made by the Secretary-General. At a panel discussion wherein HRD and marketing leaders participated, common concerns for taking cohesive actions were identified. 53 Managers from 27 Member-Companies participated actively in the two workshops.

At another Workshop on “Compensation and Management of Field Staff” 90 delegates from 37 Member-Companies participated. The delegates consisted of Human Resource Development (HRD) and Marketing Managers. The compensation profile and trends were analysed and salient features of the recent settlements were reviewed. Case studies to share experiences of the participating companies were discussed in the context of innovations in field staff management and productivity. Dr. R.B. Smarta, Director of Interlink, a well-known management consultancy firm, made a presentation on ‘Changing Profile of Field Force and Emerging Problems.”