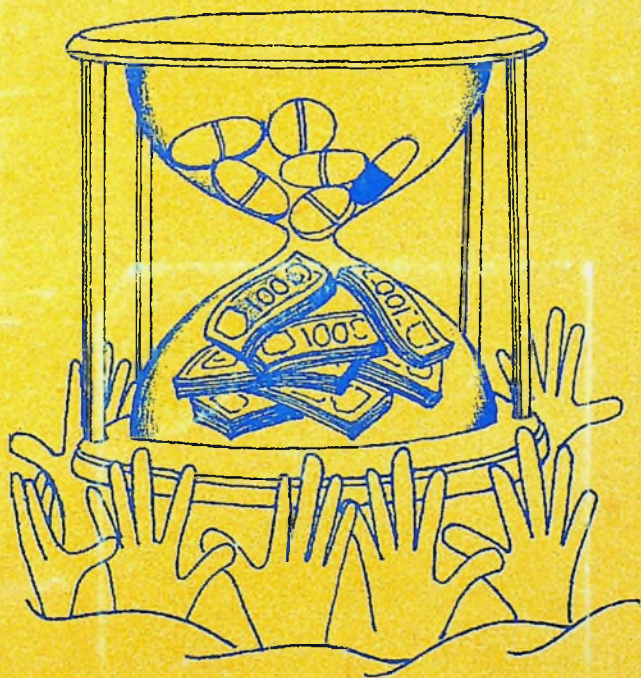


ACCESS TO ESSENTIAL MEDICINES



ACCESS TO ESSENTIAL MEDICINES

**Dedicated to the campaign of Jan Sasthya Abhiyan
for People's Charter for Essential Medicines**

**FEDERATION OF MEDICAL AND SALES
REPRESENTATIVES' ASSOCIATIONS OF INDIA**

Access to Essential Medicines

A booklet published by

Federation for Medical and Sales Representatives'

Associations of India

372/21 Russa Road East,

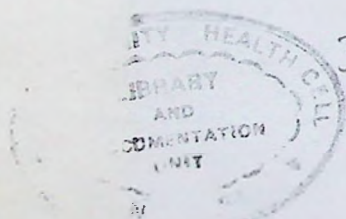
Kolkata-700 033

Phone: 4242862

Email: fmrai@vsnl.net

Kolkata, January, 2002

Price : Rs. 5.00



DR-412
07633 P02

Text by—Amitava Guha on behalf of the Drug Sub Committee of FMRAI.
Cover design—Protish Bhowmik. Other drawings have been collected from various publications of People's Health Assembly, Dhaka. Layout and printed by Satyajug Employees Cooperative Industrial Society Ltd., 13 Prafulla Sarkar Street, Kolkata-72.

Endangered Access to Essential Medicines

A serious concern has been globally expressed that the access to essential drugs are rapidly receding. There are many factors relating to health and drugs which are responsible to such situation. Most of the third world countries have become victim of the globalisation causing rapid privatisation of health when survival has become profitable commodity to the investors. The investors in health and drugs are now multinational corporations who are rapidly capturing the third world countries with the help of conditionalities of World Bank, World Trade Organisations, etc.

Nations in the third world are being compelled to change their domestic laws or policies to allow free profit earning of the multinationals at the cost of health of the people. Even the United Nation organisations like World Health Organisation (WHO) is heavily influenced by these agencies for the benefit of the business interest of the multinational companies.

In recent times, it has been established that the multinational drug companies do not bother for human life, if people die due to lack of affordability to medicines even when epidemic outbreaks. Some countries have taken bold steps in ignoring the dictates of international agencies. In contrast, the government of our country have started changing laws and policies to enable the World Bank and WTO for making profit out of the illness of our people. It is a serious concern that even if someone pays, there is no guarantee for getting an appropriate medicine of good quality.

It is, therefore needed that a campaign should be built up for appropriate policy aimed to benefit the people not only the industry. For the purpose, we have taken this step to introduce the issues regarding endangered access to essential medicine in this booklet.

**FEDERATION OF MEDICAL & SALES
REPRESENTATIVES' ASSOCIATIONS OF INDIA**

Globalisation & Health

Without considering the issues of health, drugs and its need could not be addressed. The modern technocentric, specialist dependant and drug dependant health concepts overshadow most of the vital areas of drug need. To begin with, it is therefore, necessary to understand the politics of health.

Major Players in Health: In the recent times World Bank has become the largest single investor in health. Concern was expressed in The Lancet in its July 1993 issue that this effort of World Bank may influence health policies of nations. British Medical Journal in its 27th March 1999 issue stated that 'Since 1990 the bank's health, nutrition and population division has lent \$9 billion to the health and usurped the World Health Organisation's leadership role in developing global health policy.' Intervention on health has come an obvious package of globalisation as conditions of loan. For the last several decades the International Monetary Fund (IMF) and World Bank are the major players in making decisions and managing debt policy for the third world. They have functioned as an important instrument for the developed countries of South for dominating world economy and earning higher profit. Between 1980 and 1992 the World Bank has made profit to the extent that its net earning rose to 172% to over \$1.6 billion. The accumulated earning of the World Bank amounts over \$14 billion.

Who has gained from the economic domination of IMF/Bank? It is obviously the multinational corporations (MNCs) of UK, USA and Japan. These MNCs have gathered enormous wealth which surpasses wealth of many countries. Sales of General Motors yearly is \$164 billion which is more than the Gross Domestic Product of Thailand and Norway. The market value of Microsoft is \$507 billion which is much higher than GDP of our country. These MNCs alone thus became much powerful to dictate internal policies of the countries of the third world.

IMF and World Bank forcing policy changes:

World Health Organisation (WHO) is an United Nation's body created for helping the nations for developing proper health systems with appropriate technology support. All member nations have equal right in decision making and they support with financial contribution fixed according to their own ability. Largest contributor is USA. WHO has been helping the nations with required funds for improving their health situations to attain health for

all. From the mid-eighties, the IMF and World Bank combine has also been contributing to provide loans for healthcare, sanitation and control of diseases. In tune with the IMF's structural adjustment programme, World Bank in 1993 in their annual report devised a detail document for the developing countries titled as 'Investing in Health'. By the end of eighties the World Bank became the largest investor for health. Fundamental objective of the structural reform prepared by IMF are-

- more privatisation
- reduce subsidies in the welfare activities
- devaluation of currency
- export orientation at the cost of consumption need of the people
- liberalisation for aggression of domestic market by the multinational corporations
- reduction of employment

Economic stability of countries after country collapsed while following these directives even causing political unrest.



There is no instance in the entire world that any country has gained in any way by following the directives of IMF.

In tune of the above prescription of IMF, World Bank in their report directed the developing nations to adopt major changes in their own health policies. It aimed to develop private-led health infrastructure so that the role of the government significantly reduced and the health sector is

allowed to be utilised by private sectors for earning profit. Even in the developed countries health and education are considered as social investment for benefit of the country though the imminent benefit may not be visible. But for the developing countries it was made mandatory to transform health sector for earning profit. The conditions of World Bank for loan had forced the third world countries to change domestic health policies despite knowing that these may cause immense harm to the people.

It is envisaged in the policy that practically no health benefits should be

given to the people and user's charges should be imposed for every bit of healthcare utilities. Priority should be given to the profit generating sectors. No much scope should be given to the old and unemployed sections, which do not contribute to income generation. Schemes for eradication of prevalent and communicable diseases particularly preventive measures can not generate direct profit and hence they should not be kept in the priority sector. Countries are advised to introduce health insurance system for which the foreign insurance sector should be allowed to invest. It is beyond any justification that where vast majority of people live under poverty line and remain partly or wholly unemployed, how health insurance system would be available to them.

Instead of improving health conditions of the third world countries, World Bank loan and their conditions are causing subsequent changes in domestic policy and had created all-round deterioration of health situation in these countries. Prices of healthcare and particularly prices of medicines have gone up so high that mortality rate in some African countries are expected to go back to that of seventeen years back.

State of health in our country:

While preparing 'Draft National Health Policy-2001' our Govt. have admitted that 'Malaria has staged resurgence in 1980s before stabilising at a high prevalence level during 1990s. Over the years, an increasing level of insecticide-resistance has developed in the malarial vectors in many parts of the country as a whole. In respect of TB, the public health scenario has not shown any significant decline in the pool of infection among the community, and, there has been a distressing trend in increase of drug resistance.' The new factor added to the list is HIV/AIDS about which the Govt. has no proper estimate but by all means it is increasing at an alarmingly high rate in a very short period. Common water borne infection like gastro-enteritis, cholera and some forms of hepatitis continue to contribute a high level of death.

Health Policy

Our existing health policy was declared in 1983. This policy emphasising the need of primary health decided- "India is committed to attaining the goal of 'Health for All by the year 2000 AD' through the universal provision of comprehensive primary health care services."

In the mean time, the pattern of disease insurgence has been changed. Importantly with the influx of World Bank money in health, pressure on policy change has also mounted. Our government in September,2001 had

prepared a new drug policy and put it in the internet asking for suggestions to be reached within a month. A policy that was required to be changed amidst the complicated national and international situation was at last prepared after seventeen years. Health comes under the list of concurrent subject-for both the central and state governments where the state governments bear major responsibility. While preparing this draft policy, the government had ignored the National Council of Health and Family Welfare that consists of representation from each state of the country.

In preparing the last national health policy in 1983, the Health Ministry sought for the help of two premier institutions like Indian Council of Medical Research and Indian Council of Social Science Research. Now this policy is formulated from the recommendations of the 'Policy Framework for Reforms in Health Care' drafted by the Prime Minister's Advisory Council on Trade and Industry headed by big industrialists like Mukesh Ambani and Kumarmangalam Birla. It is obvious that the policy would not necessarily depend on the interest of the poor people.

The draft health policy can be divided in to two major parts. The first part deals with the health parameters and conceptual area while the other part deals with the recommendations for implementation. There is no co-relation among them. Problems described in one part do not provide remedies in the other. The first part admits that though a few diseases could be eradicated in the last two decades but resurgence of malaria and spread of multidrug resistant TB and HIV/AIDS have become a serious concern. Along with this, water borne diseases like diarrhoea, cholera and hepatitis have increased. Diseases those were confined to the urban areas have spread in the rural sectors also, thereby the disease pattern has taken up a new shape.

The policy draft described that the health expenditure of the government as percentage to GDP has declined from 1.3 percent in 1990 to 0.9 percent in 1999. In fact, in India lowest expenditure of the government is made in health. In the developed countries this expenditure is 8 percent and even in the countries of sub Saharan countries of Africa it is at least 5 percent.

It was confessed that the health infrastructure is highly inadequate to meet the need of the people. It has been estimated that less than 20 percent of the population seeks the Out Patient Department service and less than 45 percent avails of the facilities for in-door treatment in public hospitals. There is dearth of doctors, nurses and other paramedics. The draft policy dealt with many other topics like, medical education, urban health, mental health, medical research, diseases surveillance, etc. which are all relevant. But the most unattended area in the draft is primary health and community health. Due to this shift, the policy can not reach to the objective to provide better health to the people. This has been done with an intention.

In the other chapter of the draft policy, no cognition was given to the problems mentioned in the first chapter. For example, it is recommended that only 2 percent of GDP should be spend for health. This amount takes us to the level of 1990 only and noting more. Though decentralised health structure was recommended but disease eradication and other national programme shall remain under the domain of the bureaucrats of the central health ministry. Issues like mother & child health, child nutrition, etc was not found worth to mention even.

Ours is the most private dependent health care system in the world. Our government has far less control in health than USA, UK or even than that of our neighbouring country like Sri Lanka.

Country	% earns less than \$1 day health expenditure	Infant mortality/1000	% of public exp. to total
India	44.2	70	17.3
China	18.5	31	24.9
Sri Lanka	6.6	16	45.5
UK	nil	6	96.9
USA	nil	7	44.1

Source: Draft National Health Policy- 2001

The Draft policy gave much importance to privatise the already highest privatised health system. It is proposed that to attract foreign currency, private health enterprises would be encouraged to develop sophisticated health institutes. They would be given all facilities as applicable to export oriented industries. Private owned large hospitals have been developed in some countries of Southeast Asia where no common people have any access. Similarly promotion of private insurance companies to invest in health is also recommended. In a country where unemployment is ever increasing, wide spread poverty is also expanding and more people are loosing jobs due to policy of the government how health insurance can improve the situation.

On medical education, highest priority has been given to post graduate level. Highly specialist dependent health system may serve the purpose of expensive private sectors but not the common people. The policy suggested that two more specialisation should be introduced namely, 'public health' and 'family medicine'. Without education in these two subjects no one can imagine a graduate doctor. Therefore specialisation is not necessary.

Policy also recommended on medical research. Instead of developing

research on social medicines, the policy referred to research on developing drugs. This should be the purview of the drug policy. The draft recommends that government funded medical research should be to a level of 1 percent of the total spending by 2005; and thereafter should be increased to 2 percent. This amount is highly insufficient as it is mentioned that several million dollars are required to develop a new drug whereas the draft hopes that with this paltry sum, drug development would be possible for not only one but for TB, malaria and even for AIDS.

The only area where the draft policy had made bold recommendation is on impact of globalisation on the health sector. The policy expressed anxiety that strong patents system poses a threat to the health security which may increase prices of drugs and vaccines. The policy suggested that the government exert full influence in all international fora United Nations, World Health Organisation, World Trade Organisation, etc.

The other important issue that the draft policy has totally ignored is the drug policy. Present drug policy is prepared and controlled by the ministry of chemicals and fertilisers which is a industry oriented Ministry. Medicines are important part of health care. The policy frame work on medicines if not looked under the purview of health, it is bound to serve purpose of profit by the industry. The Health Ministry through its drugs control machinery is responsible for controlling the quality, prices and licensing of drugs. There is very little mention in the draft policy even in these areas. On the contrary, the draft envisaged introduction of users charges in every stages. This is simply aimed to convert the health system to profit earning sector. There will be virtually no free treatment available to vast number of TB patients, leprosy patients or even to the cancer patients. People will have no choice to suffer painfully to die without any health care.

Rational Use of Drugs

Pharmaceutical system has become highly dynamic since there is always introduction of new better drugs replacing the old drugs. It is also a fact that with more wide use of a drug, its illeffects manifest when it is considered as hazardous drug and a decision needs to be taken to either withdraw the drug or to replace it with newer drugs with more efficacy and less illeffects. A drug may also become irrational if it is applied to wrong diseases.

The above fact is often over looked for the interest of the industry. In our country a very large number of drugs are found which are either irrational or hazardous and should be withdrawn from the market. It is observed that in most of the developing countries where resource is limited spending money for these kind of drugs is a big waste. In 1985 WHO in the World Health

Assembly decided that a list of essential drugs should be prepared by them and all nations also should prepare a list of essential drugs suitable to treat most of the diseases of which majority of people suffer. Since then WHO has prepared the list of essential drugs which is revised once in every two years. Despite assuring the WHO, our government did not prepare the list of essential drugs suitable for our people. Many organisations in the health movement demanded that such list should be prepared immediately. Only in 1996 a list was prepared but no one knows about such list and the government is also not interested to use the list. It is expected that the government should ensure production and availability of these 279 essential drugs at cheaper price.

It is also essential that the concept of rational use of drugs is included in the medical education and the government should enforce priority use of these drugs in all level. Sales of the irrational drugs in our country is very high. From the data available from Operational Research Group which audits sales of drugs in the chemist shops shows that vitamin tonics, pain killers, sex-hormones are sold in large number than the anti-TB drugs or vaccines.

Therapeutic Group	Market Share %
Antibiotics	15.50
Anti-inflammatory & analgesics	7.38
Vitamins and minerals	7.26
Cough & Cold	5.14
Antacids	4.23
Cardiac	3.69
Anti-TB	2.83
Anti-anaemic	2.82
Sex hormones	2.07
Hypotensives	2.23
Vaccines	0.83

Source : ORG, Dec. 1997

This shows that irrational use of drugs is a big problem in the country. From the list of most highly sold brands of drugs it can be found that most of the top selling drugs are irrational.

Banned and hazardous drugs

There are large number of drugs which are not only irrational but dangerous also. They are being sold without any hindrance and captured good sales. Taking advantage of weak, inadequate and faulty law dishonest business practices are let loose to sell such drugs. There is no drug to cure most of the diarrhoeal diseases, cold infection, influenza, etc. But good amount antibiotics, anti allergics, vitamins and tonics are uses for these diseases which is not only waste but may worsen disease progression. A tendency of prescribing vitamins for any ailment is not rational. Lot of adverse criticism about using vitamins at random has reduced use of conventional vitamin mixtures but new types of drugs are now promoted. Combination of Zinc, selenium, low dose Vitamin A and various forms of calcium are replacing the conventional vitamin mixtures. Some are more harmful and all of them are more expensive.

The process of banning these drugs are very difficult. In our country some drugs have been banned only when they were challenged in the court of law landing to lengthy legal process spread over years. Even if some drugs were banned but some producers including the multinationals found method to market them. For example, the government banned combination of Vit B₁, Vit B₆ and Vit B₁₂. But the producers added other vitamins with this combination and freely marketing them. A list of some drugs banned is given below.

1. Combination of Panchreatin or pancreatic enzymes with any other enzyme: Brands available in the market-Digiplex-T; Enzer Forte; Festal; Merkenzyme;
2. Combination of Phenobarbitone with anti asthmatics.
3. Combination of Penobarbitone with Hyscamin, or Belladona.
4. Combination of Nitrofurantoin with Trimethoprim.
5. Combination of Nalidixic Acid with any antiameobics including Metronidazole. Brands:Aldigram; Basigyl; Bactomet; Genogyl-N; Gramoneg-M; Gramogyl; Microneg; Nagyl; Qugyl-N; Spagyl.
6. Combination of Loperamide with furazolidone.
7. Combination of Cyproheptadine with Lysine or peptone.
8. Combination fo Diazepam with Diphenhydramine hydrochloride.
9. Combination of Metochlorpropamide with Aspirin or Paracetamol.
10. Combination of Nimesolide with Paracetamol.

It may be noted that a large number of drugs which have high sales in the market but are more dangerous or more irrational which is consciously overlooked by the authority and are freely enjoying sales and profit thereof.

All these established that there should be strict regulation for banning of

drugs. It is also required that all drugs available in the market should be periodically screened and objectionable drugs must be withdrawn forthwith. It is also necessary that before marketing any new drugs or a combination of drugs the producers should establish its therapeutic validity.

How bad drugs are sold

The drug companies use various marketing techniques ethical or unethical to promote their irrational drugs. Some methods are discussed here.

Use bias information: The companies use literatures excellently printed and projects misinformation in a most authentic manner. Tall claims are made about the benefits of their drugs. Sometimes they quote partly from the medical journals and in many occasions they were found to quote from some obscure journals which has no international recognition. Many a times they simply quote data on (their own) files. It is surprising that many persons are convinced with such misleading information and happily prescribe them.

Neurobion Forte



**Help maintain structural
& functional integrity
of neurons.**

MERCK

Neurobion Forte

50 Tablets

Each film coated tablet contains:
Thiamine Mononitrate IP 10 mg
Pyridoxine Hydrochloride IP 8 mg
Cyanocobalamin Friturate in Gelatin equivalent to
Cyanocobalamin IP 15 mg
Nicotinamide IP 100 mg
Calcium Pantothate IP 50 mg
Colours used: Ponceau 4R Lake and Titanium dioxide
Appropriate overages added

Dosage: One to three tablets
as directed by the physician
after meals.
Store in a cool, dry place.

M. I. No. 144
Manufactured by
E. Merck (India) Limited,
M.D.C. Taina - 416 208
* Licensed user of T.M.

P 2213



B No T7501
MFD FEB 01
EXP JUL 02

MERCK

The above is an example on promotion of combination drug with Vit B₁, Vit B₆, Vit B₁₂ which is banned. But the German multinational, E. Merck sells the drug yearly of Rs.35 Crores. Without mentioning any reference they have claimed in the literature that 'Neurobion'- " help maintain structural & functional integrity of neurons". It gave photographs of three persons- one is an alcoholic, the other is an age old and another is suffering from muscle cramp. No standard medical literature says that such combination can cure alcoholic neuritis, senile dementia or relief muscle cramp.

Entertaining the Doctors: Most unethical task practiced by almost all drug companies are entertaining the doctors in various ways. They invite them for wine and dine parties. It is a pity that all such parties are always over crowded by the doctors. One such example is given here showing that the doctors are invited in a cruise party in the river where wine and dinner would be served along with various other entertainments.

Cruise in River Hooghly

Away from the hustle 'n' bustle of city life... Intimidating clocks threatening to reduce your lives to a series of monotonous rigid schedules and planners, routine work... day in and day out, relentless drudgery... visualise spending an evening in gay abandon right in the lap of nature sheltered by an azure sky spanned with little wisps of clouds... a truant star peeping out at you... a cool breeze ruffling your hair and... feasting your eyes on immense stretches of water... What could be more invigorating...enlivening...paradisiac!

We at _____, or we the _____ TEAM endeavour to transform these visualisations into reality for YOU, Doctor!

We request the pleasure of your company and that of your loved ones on a river cruise along the river Ganges/Hooghly on December 23, 2001 at 4:00 p.m. aboard M.V. Sumangala.

with

Gifts and bribes: Nowadays the companies openly offer money or gifts for prescribing their drugs. Direct relation is made with the doctors with offer to prescribe their drugs for which they would get a percent of share in cash or through gifts. Now companies are spending in direct deal with doctors than making efforts to communicate scientific information.

All these actions have serious repercussion. Any prescriber who joins drug companies in the deals would try to prescribe as many drugs as possible in the shortest possible time. That means that they would not hesitate to prescribe drugs to the patients who do not need them even. This

Dear Colleagues,

Sub: Budget allocation against special gift for Doctors

As informed during the recent Sales Promotion meeting a sum of Rs.10,000/- has been allocated for each territory towards special gift for doctors. This amount of Rs.10,000/- will have to be submitted by the 31st October 2000.

In order to utilize this budget you have to write to your District Manager the name of the doctor along with the products for a supporting, and the value of business per month generated through him. It should also include the gift that you would like to give along with its cost and what additional business can be expected from the doctor against this gift. You may utilize this amount to gift two or more doctors as per the potential. Distribution of these gifts will be subject to approval of your District Manager, Regional Manager and Bombay Office. Utilization of deal (gift) items as gift for doctors will also be a part of this budget.

In addition, we have also made state-wise allocation of funds for CME, Medical conference participation, Doctors sponsorship, Journals/Magazines for doctors, Diabetes / medical camps and advertisement. You may therefore, get in touch with your District Manager / Regional Manager for organizing these programs. They will help you in the optimal and judicious utilization of this budget for best returns.

Please note, that a Glucometer has been provided with each Sales Manager / Assistant Sales Manager and separate samples of Glucose will be provided to you for organizing diabetic camps. Please write to Bombay Office after discussing with your District Manager/Regional Manager for your requirement.

Also if required, arrangement for Glucometer can be made to your Regional Manager if proper utilization can be guaranteed for atleast 10 camps in a year.

Make best use of this allocated budget to generate maximum product range prescriptions, which will help us in recording significant growth.

Regards,



PS: An advance of Rs.20,000/- for each ARM/RM/ASM/SM has already been provided for effective implementation.

may endanger their life. The drug companies are corrupting the medical profession rampantly.

Patent System and Impact on Drugs

What is Patent: Patent is a right conferred by the government to inventor for a certain time for a product or process to produce it, for commercial utilisation of the invention. It is argued that patent is given to the inventors for his investment of his talent and cost for his invention. In reality, patent is a monopolistic right and is optimally utilised by the

multinational drug companies to exploit the developing countries.

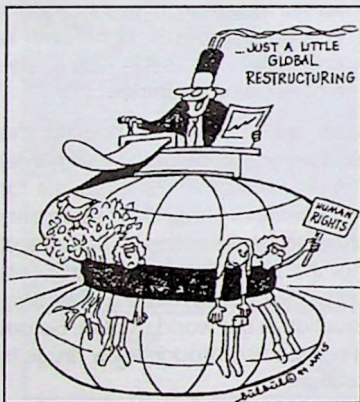
Indian Patents Act, 1970: This Act is well known for helping the development of Indian pharmaceuticals industry and considered as a model Act for the developing countries. This Act do not permit 29 materials for patenting of which drugs and agricultural materials are important since they are concerned to human life. The Act only permits patenting of process of producing (Process Patent) a drug but not the drug (Product Patent). This has given a scope to the Indian drug companies to introduce a new drug within two to three years of their first introduction in the world market. Before the Act was developed, the multinational companies brought new drugs in India 10 to 12 years after their first introduction.

Provision like Compulsory Licensing in the Act is very significant. According to this, if a drug is found to be very important for public need, the Govt would allow any person other than the patent holder company to produce it provided he gives royalty to the patent holder. Indian drug companies could get a chance to develop the process of manufacturing new drugs and started producing them in our country. This could not only give the scope to produce new drugs but the prices of the drugs became more competitive. In fact, in India prices of drugs are even now is one of the cheapest in the world.

The Patents Act also provided the scope to the Indian national sector industry to flourish and now almost all essential drugs are produced in the country. Not only this, many drugs are now exported by the Indian companies in the developed countries. The pharmaceutical market in our country was dominated by the multinational companies. Now the Indian companies have successfully competed the multinationals and established their domination in the domestic country. Out of the top 50 drug companies at least 25 are Indian Companies. Some Indian companies have been able to establish production units in other countries also. Indian companies have also established research laboratories. Some of the companies have even developed drugs in biotechnology route and patented them. India has become self reliant in the drug industry. This is a unique situation not found any countries of the third world.

WTO and Access to Essential Drugs:

The Associations of multinational drug companies in USA, Europe and Japan has strongly lobbied to include patent in the GATT system. GATT was a platform to negotiate trade among the countries. There was no basis to



include the monopolistic right like patent in the trading system. Only objective of this was monopolistic capture of the market in the vital area like drugs. WTO Agreement finally provided such scope to the multinational drug companies. The multinational companies had utilised. Patenting system in many developing countries by compelling them to import drugs from the parent countries of the multinationals. They took patent of their drugs in these countries and never cared to produced them in these countries. With the help of weak patent system in these countries, they did not

allow any others to manufacture even if they were able to produce them indigenously. Many countries had suffered form this to the extent that they were not able to supply drugs to control epidemic situation. Tragic deaths have taken place when they could be avoided by simply supplying appropriate drugs at cheaper cost.

The WTO Agreement compels all the member nations to enforce a strong patent system which would not allow compulsory licensing system and parallel import. It was possible earlier to import cheaper drug from any country if the drug of the patent holder was found costly. This is known as

parallel import. The imminent result of WTO was found in South Africa where nearly 25 percent population suffer from HIV/AIDS. People were dying of this disease for high cost of drugs. Even due to high price of miconazole, drug needed to treat fungal infection in the mouth, AIDS patients were dying. Pfizer, a US company, priced this drug very high. Apart from this, three drugs regimen required for treating was patented by multinationals like Bristol-Mayer, Glaxo, etc. Costs of therapy of all these drugs were as high as \$11,000 per year. Large number of AIDS patients in South Africa were dying as they could not afford such high cost. When South Africa started importing these drugs from India which offered a cost of \$350 per year only, 38 multinational companies filed case against government of South Africa. Global voice was raised against such inhuman action of the multinationals. Finally the case was withdrawn. Not only this, some of the multinationals declared that they would reduce the prices of their drugs. It was thus established that multinational drug companies were charging very high for their drugs.

In recent time when US government was facing the threat from large scale anthrax infection, drug like ciprofloxacin was needed. Indian companies offered very low price for supplying the drug. At this point, the original patent holder of ciprofloxacin, Bayer negotiated with US government and offered a low price but not lower than the price offered by Indian companies.

All these instances exposed that the multinational drug companies are keeping the prices of their drugs high and would not bother the national emergent situations.

Role of Public Sector

After independence, our Govt. requested the western countries to develop pharmaceutical production units in the country. When none of them came forward, WHO and UNICEF helped the Govt. build first public sector drug company, Hindusthan Antibiotics Ltd. (HAL) in the year 1958. Some times later with the help of former Soviet Union another public sector drug company, Indian Drugs & Pharmaceuticals Ltd. (IDPL) was developed first in Rishikesh and later in different parts of the country. IDPL was the largest pharmaceuticals factory in Asia. It was capable to produce many drugs, had a research and drug development infrastructure. Many small and medium drug companies also came up where large amount of bulk drugs were supplied by these companies.

As a result of this drugs of quality became available at much cheaper price. These companies were catering the need of Govt. procurement of drugs and thus a lot of money could be saved. Govt. gave all priority to these

companies. In due course of time, due to competitiveness, foreign drug companies started their drug production units in our country.

Right from the beginning, conspiracy was hatched to destroy the public sector drug companies. Lack of accountability, inadequate marketing plan and corruption started eroding these companies. By mid eighties, the Govt. ceased from giving priority to these companies and allowed the other private companies to earn profit at the cost of these public sectors. The Govt. also took over three other private companies namely, Bengal Immunity, Bengal Chemicals and Smith Stanistreet to save their sickness. Later the Govt. started to neglect these companies also.

HAL was a profit earning company, but the Govt. allowed the company to wrought and showed it as a losing company. Now the company is given on lease to Max GB and RPG Health Care which are making profit out of this so-called losing company. The tragic situation was created in IDPL which remained closed since 1996. This has forced the country to import a large amount of drugs like tetracycline, Vit B₂, Vit B₆, Folic Acid, etc. A large number of workers, technicians and scientists became jobless. The Govt. institutions are now forced to buy drugs from the private companies at much higher price.

Drug Prices

Prices of drugs had always been considered as the most important factor for earning profit. Due to the development of pharmaceutical industry in India and the priority role played by the Public Sector drug companies, prices of drugs here remained one of the lowest in the world. The Central Govt. first in the year 1970 kept all drugs under price control. Following the first drug policy declared in 1978, the Govt. kept 387 drugs under price control announcing Drug Prices Control Order (DPCO). There was tremendous resistance against DPCO from the drug companies particularly from the multinationals who went to court to stall the price control order. Many of them stopped production of essential drugs to create a crisis. Subsequently the Govt. in their DPCO 1986 reduced the control on only 167 drugs. This resulted to rise of prices of many essential drugs immediately. The Govt. argued that market competition would not allow rise of prices. In fact pharmaceutical market is always dominated by brands, which is established by high-pressure marketing technique used by the drug companies. The drug companies continued their pressure in this area and was successful in reducing the span of price control further. In the DPCO 1994 the Govt. kept control on prices over only 63 drugs. Recently the Govt. constituted a committee to review DPCO. The committee travelled several developed countries to find out the state of price control and commented

that prices of drugs are directly or indirectly controlled in all countries. Even though, the committee recommended that there should be a mere notional control on drug prices in India.

It has been found in several occasions that the drug companies have been deceiving the Govt. in submitting the cost data of their drugs. Immediately after 1986 Drug Policy was introduced, through court case it was revealed that well known multinational companies like Hoechst, Glaxo, Pfizer, etc. had highly over charged prices of some of their bulk drugs. Some of the instances are given below.

Company	Drug	Price Shown	Actual Price	% over Charged
Glaxo	b methasone	Rs.1,10,00	Rs.2,20,000	100
Hoechst	Baralgan	Rs. 24,735	Rs. 1,810	1267
Boehringer	Euglocon	Rs. 9,800	Rs. 2,450	300

The Supreme Court directed the government to recover such overcharged amount which stood at that time a total of Rs.200 crores. But the government could not do much in this regard. As a result, many other companies continued to over charge their drugs even violating the Price Control Order. Recent reporting in the news papers on this issue states that "the tenure of Drug Price Review Committee has been extended up to 1998 for settling the Rs. 220 crores unpaid dues by the pharmaceutical industry under Drug Price Equalisation Account (DPEA). The pharmaceutical industry has challenged the government's claim under DPCO. However, the Supreme Court in a case between Department of Chemicals & Pharmaceuticals and Cyanimid company had upheld the validity of provisions under DPCO. Notwithstanding the Supreme Court verdict and appointment of DPLRC, the government could not obtain much result in realisation from the the industry. According to an official release, till date only Rs. 22 Crores has been deposited by the industry."

Rise of prices in the recent times have been very high. A study of over 820 brands for different diseases shows that there has been rise of price in the last three years; for some drugs were about 300 per cent even. Barring few antibiotics, pain killers and drugs for gastrointestinal diseases, prices of almost all drugs increased. In a note circulated by the Govt. in November ,1997 it was stated that "Experience has shown that product wise price control mechanism has led to stagnation in terms of newer products and to proliferation of existing products in numerous different strengths and pack sizes, creating confusion in the minds of consumers as also rendering price control system impractical."

In the recent times the drug companies have successfully established a new regime of prescriptions where old and cheaper drugs are being replaced by new but of no significant advantages. These drugs are priced high and are promoted with high thrust by the drug companies. When a painkiller like aspirin costs Rs.0.30, new pain killers costing Rs.2.40 or more are prescribed.

All new drugs are highly expensive. Some Examples are-

Drug	Company	Used for	Price
Cefizox	Glaxo-Welcome	Antibiotics	Rs.315 each inj.
Magnamycin	Pfizer	Antibiotics	Rs.284 each Inj.
Lambisil	Novertis	Antifungal	Rs. 121 each Tab
Amicor	SamarthPharma		Rs.1200 each inj.
Amaryl	Hoechst	Antidiabetic	Rs.103 for 10 Tab

For drugs, patients have no choice. Prescribers often forget the affordability of the patients. It is the drug companies which pursue sales of such high priced drugs even though cheaper alternatives are available.

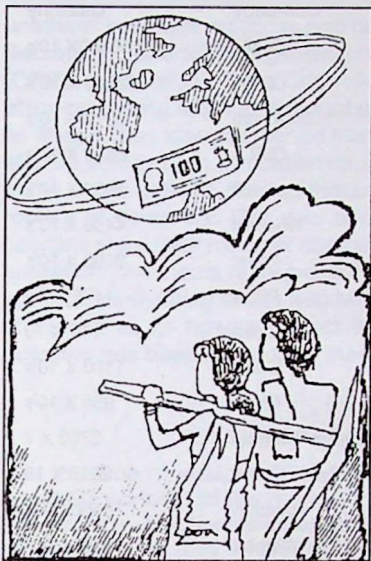
The other phenomenon which exposes that drugs are really exorbitantly priced can be found in the branded generic drugs. Some drugs are marketed by well known companies in generic names with some brands mentioned. These drugs are sold in bulk with a very a high margin of profit to wholesalers. But the retail price with which the drugs are sold to customers are same like other brands. Some examples of such drugs are given below.

Drug	Company	Generic	Pack	Price to Wholesalers	MRP	Difference %
Nausdan Tabs	Alchem	Domperidine	25X10	96.85	540	457.56
Zedonac Mr Tab	Alchem	(Diclo+para+Chlorzox)	10x10	68.05	380	458.41
Filikem	Alchem	Folic ACID	25x10	34.4	200	481.40
Aginal5	Alembic	Amlodopine	100mg	2.9	17.6	506.90
Zedonac Tabs	Alchem	(Diclo+para)	20x10	51.6	320	520.16
Cisachem	Alchem	Cisapride	25X10	119.78	902.5	653.46
Odinol AM Tab	Alembic		10 Tab	4	35	775.00
Oxicam dt	Alembic	Pyroxicam	10 Tab	3.45	31.5	813.04
Cetral Tab	Alembic	(Certrizine)	10 mg.	2.2	25.6	1063.64
Pyrimide MD	Alchem	Nimesulide 100	25X10	60.9	725	1090.48
Tab Pyrestal	Ranbaxy	Nimesulide 100	10 Tab	1.7	25	1370.59
Pyrimide	Alchem	Nimesulide 100	25X10	39.1	625	1498.47

Black Marketing of Drugs

There is a novel way to earn extra profit by the drug industry by unethical business practice. It may not be exactly called as black marketing which in

traditional experience is hoarding and selling of goods at inflated price. In drug industry it is done in a different way. One of the processes is to sell drugs with extra unofficial discounts. This discount is given with the consent of the officers at the head office so that some favored wholesalers lift more goods than the usual to earn the extra discount. Huge amount of stocks are sent to some selected wholesalers who in turn sell them to wherever possible. Drugs being sold under maximum retail price, there is no relief available to the consumer out of these undercut prices. It is the drug companies and a few wholesalers who enjoy additional profit. This also establishes that in the existing price structure there remains enough profit margin which allow the companies to sell their drugs at under price.



It was found that in big wholesale markets in Kolkata, Mumbai, Delhi, Chandigarh, Agra, Varanasi, Kanpur, etc. drugs, particularly injectable are sold in cheaper price. People do not know how this happens. There are instances that the big drug companies when manufacture their drugs under third party license in another company's factory, there is always scope of evading excise duty. There is some other process when large amount of drugs are sent from one state to other where sales taxes are lower. Thus it is established that selling drugs evading of government duties and taxes are possible and finally it is found that there is proliferation of counterfeit drugs. It was published in the newspapers that the authorities have unearthed big rackets in the outskirts of New Delhi those are counterfeiting the well-known brands of drugs. Consumers can not identify these spurious drugs since they are made with high counterfeiting skill. Even if someone doubts that a drug is not effectively working and it may be spurious, there is no proper way available for him to file complaint and ask for immediate remedial steps. Now it is admitted by the Drug Controller of India that a very high percent of spurious drugs have flooded the market which has a serious health hazard

potential. In a recently issued circular to State Drug Controllers, the Drug Controller of India informed that they had detected 78 spurious drugs of different brands including those of very well known companies. Some instances from the circular are given below.

Drug	Batch No.	Company	Quantity
Amoxy Caps, 500mg	G9564	Cadila	60600X 10's
Acilox, 150mg	0179	Cadila	12240 X 10's
Acipro, 500mg	ACTM0219N	Alkem	9210 X 10's
Cipolx, 250mg	Y91203	CIPLA	6630 X 10's
Combiflam	210265	Hoechst	1032 X 10's
Rulide 150mg	020024	Hoechst	4450 X 10's
Dolonex DT	020-04105L	Pfizer	3690 X 10's
Oxytetra 500mg	020-51257L	Pfizer	1475 X 4's
Phexin, 500mg	M135	Glaxo	110 X 10
Becadex Forte	H4467	Glaxo	1100 X 10's
Zinetac, 150mg	NE606	Glaxo	955 X 10's
Duphaston	LJ3176	Duphar Interfran	2700 X 7
Ciprobid	ZH9028	Zydus Cadila	2510 X 10
Mobizox	J01000	Ranbaxy	10450 X 6's
Nimesesic	91843	Alembic	10800 X 10's
Esgipyryn	9J136	Sarabhai Piramal	13800 X 10's

Drugs are procured by the Public and large institutions like hospitals in cheaper rates since they purchase in large quantities under rate contract and in some cases, drugs supplied to these sector bears no taxes. It is made conditional to drug companies that they would not sell drugs cheaper than the prices offered to the institutions. Generally it is required to write on the labels of the drugs supplied to institutions that the retail chemists can not sell them. There are many instances that the companies in the name of institutional sale raise bills and the drugs are sold to the wholesalers at much cheaper prices.

In adopting such unethical business practices, large number of the drug companies big or small are involved. This system involves top Executives down to the local level managers of the company. To compensate the undeclared discounts, adjustment is made by the managers of the company by providing physician's samples in large quantities since no taxes are imposed on the samples and cost of samples are considered as expenses of the company for promotion which again reduces income tax burden. This

situation has spread so widely that the industry is itself facing crisis. It has become difficult to conduct normal business without involving in dumping, unauthorised discounts, selling of institutional supply in the open market, etc.

It was first FMRAI which pointed out the government to take steps to stop unethical business practices and demanded for inquiry by CBI. In 1997 the Secretary General of Organisation of Pharmaceutical Producers of India (OPPI) wrote to the Drug Controller of India drawing attention about this black-marketing sales at discount prices without any bills which they states as illegal. They also mentioned that spurious and substandard drugs might also be sold in such a situation causing tremendous health hazard and risk to the public at large. Further this sales deprive state exchequer of genuine receipt of sales tax. This was enough for them and no further action is possible since their member companies are thickly involved into such illegal operation. The media reported that a group of large companies has recently formed investigating set up with Mr. K.P.S. Gill, retired Police Commissioner of Punjab as its head to detect the spurious drug racket. But so far, no outcome has been heard from them.

Role of Multinationals

At the time of independence, the multinational drug companies shared about 90 per cent of the market. Report of the Hathi Committee exposed that these multinationals established their business with a meagre amount of investment and thereafter they have spent nothing but developed a large business in pharmaceuticals industry. They have repatriated large amount of money in the name of royalty, technical know-how, raw materials cost etc. Initially they used to import all drugs but after the establishment of public sector drug companies and due to Indian Patents Act, 1970, they were compelled to establish manufacturing units in our country. The units they installed, in course of time became old and no innovation of technology was tried to update these plants. Only the capacity of the plants was expanded. In contrast, the Indian companies introduced new technology and established modern plants. Thus they were able to compete the multinationals and could share Indian market almost equally with the multinationals. Not only this, Indian companies are now exporting a number of drugs to the developed countries including the USA.

It was the multinationals which influenced in making the WTO agreement. They are now happy that there will be no compulsion for producing drugs in India following the terms of the agreement. Even before the amendment of Indian Patents Act, 1970, these multinational companies are either closing their plants or selling them to other Indian companies. As a result, large number of pharmaceutical units are closed.

CIBA Giegy :	Closed its Bhandup Plant
Sandoz:	Closed its plant at Tahne
Boehringer Mannheim:	Closed its plant at Thane
Roche :	Closed its Plant at Tardeo
Parke Davis:	Closed its plant at Saki Naka
Rhone Poulenc :	Closed all plants
Boots :	Closed all plants
Abbott :	Closed all plants
Glaxo:	Closed its plant at Thane and Worli
Pfizer:	Closed its plant at Thane
Burroughs Welcome:	Closed its plant at Bhandup

Thus nearly 40,000 workers, technicians and scientists were thrown out of job from these plants. The drugs which were produced by the multinational companies in these plants are now mostly being imported taking the advantage of liberal import policy of the Govt. It is now found that the multinational drug companies are now importing many drugs which were once produced here. According to Director General of Commercial Intelligence, since the country signed WTO Agreement, import of finished formulations have surged from Rs.173 crores to Rs.680 crores during the nine months this year.

Drug Policy

After through debate in the Parliament, the Govt. constituted Committee on Drugs & Pharmaceuticals known as Hathi Committee. This Committee made certain important recommendations. The Committee observed that the multinational drug companies are marketing many irrational drugs that too at a highly inflated price. They recommended that initially the equity of the foreign companies should be brought down to 26 percent and then gradually they should be nationalised. The Committee also prepared a list of 113 essential drugs and recommended that the Govt. should ensure production of essential drugs by giving priority to the Public Sector drug companies.

First Drug policy was declared by the Govt. in 1978, which gave priority to Indian sector particularly the Public Sector. But the Policy ignored many important recommendations needed for the people. The policy helped the Indian sector to grow substantially. Govt. research institutions like Central Research Institute (CDRI), National Chemical Laboratories (NCL) and

Indian Institute of Chemical Technology (IICT) developed process technology of many essential drugs which were taken up by the Indian drug companies. As a result, India became almost self reliant in production of essential drugs. Not only this, Indian companies are exporting large number of drugs even to the developing countries including the USA.

Following the liberalisation policy, the Govt. has abolished many decisions causing serious crisis to the Indian sector. There is hardly anything left in the original drug policy now.

Change in the Drug Policy:

The government of India has started to make all efforts for changing drug policy. Through a secret document titled as 'Pharmaceutical Policy-2001', the Govt. have shown their real intention to serve the interest of the multinational drug companies more vigorously. The document has been kept secret so that at opportune moment this can be turned into a policy in haste. It is necessary to expose this move of the Govt. The document was prepared on the basis of the report of the two Committees formed earlier by the Govt.-Drug Price Control Review Committee and Pharmaceutical Research and Development Committee. Therefore it is obvious that the future policy will remain confined to these area only.

It was mentioned at the very beginning of the document that in the era of globalisation, regulatory control of the Govt. in the pharmaceutical industry would deter growth. The document admitted that many decisions have already been taken by the Govt. which affects drug policy. They are-

- *Abolition of industrial licensing:* No Industrial licensing would be required for bulk drugs, their intermediates and formulations if cleared by Drug Controller General. This decision has affected drug industry adversely. Withdrawing of industrial license has forced the country to import more. Reservation of certain drugs for production in the public sector has been withdrawn and its consequences are already felt. Now any one, multinational or Indian sector would be allowed to manufacture any drug or intermediates in our country.

- *Foreign Investment:* The decision that foreign direct investment with 100 percent equity in pharmaceuticals industry was taken some time back. Earlier only 39 percent foreign equity was allowed. Instead of attracting foreign investment, the industry experienced a wave of de-industrialisation. Nearly all multinational companies have closed their production plants in India. But all of them had maintained their activity.

Now with the given chance of 100 percent foreign equity investment without any compulsion of production activity, these companies will happily import drugs from their parent country.

- *Imports:* Earlier drug policy had put some embargo on free import of finished formulations. The Govt. has withdrawn all restriction on import of formulation. This has allowed a sharp rise of import of drugs in our country in the last three years. There will be further jump in this figure in the near future.

- *Foreign Technology Agreement:* There will be automatic approval for foreign technology agreement in the cases of bulk drug production. There has been no response from the multinationals in technology agreement following this liberalisation. On the contrary, import of bulk drugs have increased to such extent that the Indian industry is now demanding for imposition of dumping duty on several imported bulk drugs.

It is recommended in the document that a corpus fund would be formed with Rs. 150 Crores which will provide funds for research. It was not clearly spelled as to from where this fund would come. It is obvious that this fund would be generated through tax on the people. This fund will be given to all private companies-national and multinationals. It means that people will pay for research but the drug invented would remain patented for which people will have to pay high prices. There is no similar system in any other countries. For managing this fund formation of Drug Development Promotion Foundation has been proposed. Nothing has been proposed to fund the Govt. drug research units which have invented process technology for production of largest number of essential drugs so far. It shows that the Govt. is no longer interested to encourage these premier institutions. In the document, definition of research based industry is kept in such a manner that virtually no Indian drug industry would be able to utilise such scope. For example, in order to enable such facility a company must have 100 Indian research scientists and should have ten patents to their credit. Ultimately, this advantage would be utilised by the multinational companies only.

Most of the recommendations in the document have been made in the area of drug prices. The document in the tune of the industry stated that it aims '*to remove rigors of Price Control particularly in view of the ongoing process of liberalization.*' Drug prices Control Order (DPCO) is now applicable to a meagre 63 drugs only. The spate of price rise has now become enormous. The document also spelled that any abnormal rise of prices would be kept on watch. But how the prices of drugs beyond price control could be performed has not been thought of. The document

mentioned that the price control on drugs will remain very notional only. The other process of the existing DPCO was that price of the single brand is controlled if its sale goes more than Rs. 4 crores in a year. The document recommends that this limit should be raised to Rs.20 Crores. With this immediately about 40 top selling brands would go out of price control.

Anxiety was expressed in the document about the high prices of the imported formulations. It recommended that not more than 50% profit to the landed cost of the imported drugs would be allowed. It is paradoxical since the largest amount of formulations are imported from the multinationals, the prices would be kept high much before importation. The multinational drug companies in number occasions were caught for inflating prices through transfer pricing system.

It was admitted in the document that the manufacturers provide a large amount of commission to the wholesalers which should be controlled. There is no process so far evolved by the Govt. to control the unannounced sales commission given by the drug companies. Apart from the declared commission, drug companies provide excess goods as undeclared commission where no documents are maintained. No measure has so far been recommended in this regard.

There is very little mention in the document about quality control. It was proclaimed that the Ministry of Health and Family Welfare would progressively benchmark the regulatory standard against those adopted in developing countries, for manufacturing. With the present inadequate machinery, it is impossible to assure quality control watch. The large amount of fund required for developing testing laboratories and the drug control structure in the states, it is beyond imagination that how the Govt. can think of benchmarking the standard to those of the developed countries.

The 'Pharmaceutical Policy-2001' envisaged in the document is simply a device to provide more advantages for the multinationals and complete destruction of self-reliance of the drug industry. This policy by all means should be opposed.

Interestingly, the document made its recommendations with a conjecture that Indian Patents Act has been changed totally as envisaged in the Patents Amendment (Second) Bill. The fact is that the global opinion against the IPR chapter of WTO agreement had forced the Doha Ministerial meeting to agree to reconsider changing certain provision for the shake of people's health.



People's Health Assembly

In the world of commercialisation of health and gradually diminishing of rights to essential medicines, people of different countries are fighting. In our country various groups and individuals jointly decided to campaign on health rights throughout the country. After a year of joint campaign, they came to Kolkata where a historic rally was held for the first time by the end of November, 2000. They discussed

on various aspects of health and drugs and prepared a 'People's Charter for Health'. Nearly 2000 delegates from all over the country decided to launch campaign on this charter continuously. After this assembly, 200 delegates from India went to Dhaka, Bangladesh to attend international People's Health Assembly. 1400 people from 93 countries attended this assembly, analysed the cause for failure of the international agencies like World Health Organisation, UNICEF, etc. in resisting the commercialisation of health and from deterioration of health of the people. The Assembly decided that global movement would be launched through co-ordination among the nations. The Assembly adopted a People's Health Charter for guiding the future movement and shaping of demands.

Peoples Charter for Access to Essential Medicines

1. No privatisation of the public healthcare system.
2. More per capita budgetary expenditure on healthcare.
3. Increase the number of National Diseases Eradication Programmes and enhance budgetary support to each programme.
4. Revitalise public sector drug companies.
5. Develop a public distribution system for cheaper essential drugs.
6. Formulate a rational drug policy under the aegis of the Health Ministry.
7. Ensure production and availability of all drugs in the national Essential Drug List.
8. Control imports of bulk drugs, intermediates and finished formulations and rationalise duties on imports. Restrict import keeping in view the needs of domestic producers.
9. All drugs should be assessed periodically, in order to ban hazardous and irrational drugs.
10. Formulate a new Drug Prices Control Order to bring all drugs under price control and to reduce prices of essential drugs.
11. No change in the fundamentals of the Indian Patents Act, 1970, that allow domestic manufacture of patented drugs to counter monopoly, high prices and imports.

12. Utilisation of third party licensing by big companies to evade taxes, reduce employment and utilise cheap labour should be stopped.
13. Uniform tax structure for all drugs, maximum retail price should be inclusive of all taxes.
14. Strengthen quality control mechanisms to stop proliferation of spurious and sub-standard drugs.
15. Enquire into corrupt practices by drug companies involving tax and duty evasion.
16. All government purchases should be made through a central procurement system, based on the list of essential drugs.
17. No Foreign Direct Investment (FDI) be allowed in the pharmaceutical sector, except where there is clear indication that such investment will be accompanied by transfer of technology not available in the country.

Background of People's Charter for Essential Medicines

The government of India has changed certain policies and declared that some other policies would be changed which will have direct effect on healthcare system of our country. To ease investment of the multinational insurance companies, the government had adopted Insurance Regulatory Authority Act. This is step to introduce private health insurance so that the government can withdraw its investment in healthcare for the wage earners. The government have also stated that the number of drugs under Drug Prices Control Order (DPCO) shall be further reduced

Public healthcare system is under attack. In most of the states central government's investment in healthcare has been stopped. Instead, states are compelled to accept World Bank's loan. This loan envisages that the aim of such loan is to develop private led health infrastructure in states. Some of the conditions of this loan is to introduce users' charge system purchase of medicines for foreign countries. Money invested by the World Bank has to be realised for the patients and the debt is to be repaid within 25 years with 5 per cent interest.

Already actions are taken in the districts and states to gradually shift the administrative responsibility to private organisation and groups tasking away the role of authorities elected by the people. This will pave the way for the commercial enterprises to take over the public health infrastructure. Interference of the World Bank in health has caused forced changes in national health policy and ruined better healthcare systems in the countries of Latin America which is to some extent admitted by the World Bank also. Therefore the government should stop such investment of World Bank and provide responsibility to manage health system keeping the objective of primary health care by giving more power to local self-governments.

Government's budgetary investment in health has come under two percent of the budget. Per capita investment in health is only Rs.57 a year whereas the Govt. spends ten times more in military investment. India's expenditure in health is one of the lowest in the world. The Govt. has not only

reduced expenditure for eradication programme for diseases but reduced total number of programme also. While spread of disease had not remained confined in the traditional areas but epidemiological concern is found in newer diseases. Therefore national diseases eradication programme should be expanded for more diseases and expenditure should also be enhanced.

Instead of the appropriate Ministry, the Finance Minister announced that the drug policy would be changed. This is simply under the direction of the industry not for better health of the people. Since first introduction of drug policy in 1978 subsequent decisions of the Govt. in this area was to curtail the provisions of the policy to accord the benefit of the industry. Virtually the drug policy has now been made redundant. The Govt. had appointed two committees- one to prepare policy on R & D and the other for review of the DPCO. Both the committees have prepared their recommendations. The committee on R & D among other recommendations proposed to constitute a corpus fund of Rs. 150 crores for its distribution on R & D of private farms. Role of private farms in developing new drugs is devastatingly poor. Whereas the Govt. research institutions contributed significantly in developing process technology for nearly all essential drugs rendering Indian drug industry almost self reliant. They have also invented several new molecules. The Govt has not yet decided as to how to develop this large fund of Rs. 150 crores. It is apprehended that this fund would be created by imposing more taxes on drugs. Thus private enterprises will be allowed to benefit more by increasing the prices of drugs. It is therefore needed that the Govt. Should invest more for research by the Govt.'s own research organisations.

Till today, largest drug manufacturing structure is maintained by the public sector. The Govt. rented out most of the production units of Hindustan Antibiotics Ltd. to private enterprises who are making profit out of it. Indian Drugs and Pharmaceuticals Ltd. (IDPL), the largest drug producing company of India has been kept non-functional since 1996. Now BIFR had recommended to close this company. These two public sector companies have been producing largest number of drugs helping the country to attain self reliance. These companies also helped small scale drug units by supplying rawmaterials at cheaper price. Keeping these companies idle has forced the country to import many drugs. It is therefore needed to prioritise the role of the public sector drug companies by revitalising them which also include Bengal Chemical, Bengal Immunity and Smith Stanistreet for producing bulk drugs, vaccines, and formulations at cheaper price.

The Govt. should also establish public distribution system of drugs. In this vast country, access to drugs in remote villages does not exist. All essential drugs at subsidised price should be distributed through chain of retail stores in the interior places.

Keeping aim to rational use of drugs, the Govt. should prepare a new drug policy. Regulatory authority for this policy should be the health ministry instead of the industry ministry. The policy should aim to cater the need of drugs based on the list of essential drugs. It should ensure production of quality drugs at cheaper prices and minimise import. The policy should also

devise process of utilisation of the rational drugs by the medical profession and pharmacists. Large number of hazardous and irrational drugs floods present-day market. This has been possible due to laxity of Govt. law and by the high-pressure unethical marketing practices by the drug companies. In absence of appropriate law and vigilance of the Govt. the manufacturers are freely promoting these drugs without following any ethics. Though the Govt. assured World Health Organisation that the Govt. would prepare appropriate regulation following the 'Criteria of Ethical Promotion of pharmaceuticals' prepared by WHO, but no such steps have been taken so far. In the recent years tendency of marketing highly priced new drugs has spouted up. Most of these so called new drugs do not have any significant new efficacy than the existing drugs but are priced high and fetch more profit. Various kinds of inducements are used to promote these drugs. Many of these drugs are imported. Therefore the drug policy should include criteria of ethical drug promotion and stop import of hazardous and non-essential drugs.

Due to liberalisation of import, the multinational drug companies are closing down their production units in the country and these drugs are either imported or partly being manufactured in the small scale companies. This has enhanced import of drugs manifold in the last two years. Closure of large production units has caused unemployment of thousands of workers. Further, merger, acquisition and brand selling had closed many production units. On the other side investment in the industry remained insignificant. All these situations together have created severe unemployment and severe loss of job security. Cheaper bulk drug import has also forced closure of many medium sector bulk drug companies. Therefore the Govt. should take proper measures to stop rampant import of bulk drugs and impose anti-dumping duty. Drugs, which are manufactured indigenously, should not be allowed to import. Import norm for drugs should include validity clause and remodelling of duty structure should be worked.

There has been sharp rise of prices in the recent years. Prices of essential drugs like anti-TB, anti-leptotics, cardiovascular drugs are rising every year even more than the rate of the raise of prices of other commodities. Span of DPCO is reduced from 387 drugs in 1979 to only 75 drugs in 1994. There has been raise of prices of drugs under control category also. The National Pharmaceutical Pricing Authority (NPPA) reduced prices of some drugs after examining cost data provided by the manufacturers. Most of the manufacturers are reluctant to submit cost data of drugs. Apart from this, the Govt. machinery for analysing cost data are highly inadequate. Taking this chance many drug companies are openly flouting DPCO and enhancing prices of drugs. Even though the Govt. has declared that they would reduce the span of drugs under DPCO. The review committees on DPCO constituted by the Govt. only worked up on the procedure of quickening the price rise. Industry has attacked NPPA which would be liquidated soon. It is therefore needed to formulate new DPCO aiming to reduce prices of all essential drugs and to control prices of other drugs also.

Indian Patents Act, 1970 has helped the country to achieve self reliance in

production of drugs. This has also helped introduction of new drugs almost simultaneously to their first introduction in the world market. This act has encouraged development of process technology by the Govt. research institutes for nearly all essential drugs. It has also helped reducing the prices of drugs. The Govt. with a plea of threat from WTO has been all set to change the Act thoroughly, which will reverse the benefits achieved due to this Act. Even now, many provisions of WTO can be bypassed by carefully pursuing the need of the people for survival. The clauses of compulsory licensing and automatic licensing right are vitally required for self-reliance of the industry. Scope of parallel import of drugs should not be given up. In the recent occasion some countries have withstood the threats of the multinational drug companies to provide the essential drugs to the people. India should not succumb the unique benefits of Indian Patents Act, 1970.

The Govt. had allowed the industry to manufacture drugs in small companies even if they have own manufacturing units. Taking this opportunity many large companies have closed their factories. This third party manufacturing provides the big companies to utilise exemptions provided to the small scale. They also exploit the cheap labour cost of the small scale. On the top, the question of quality and giving rise to spurious drugs has now become a big question. Complaints have been made that with this process large quantity of drugs are sent to market without paying any taxes and duties. This has posed a serious question on health hazard. Demand was made to the Govt. to constitute enquiry on selling spurious drugs and selling of drugs with unannounced discounts and by various unethical process of dumping drugs in the market. No actions have been taken by the Govt. so far. Both the Govt.s at Centre and states are losing several crores of rupees in taxes and duties because of these unethical sales. Even the associations of the industry and trade had not denied that such activities are taking place.

The tax structure on drugs is anomalous. It varies from state to state which is another reason for illegal proliferation of drugs from one state to the other. While buying drugs people are charged according to the whim of the sellers. It is therefore needed that there should be uniform tax on drugs and the price printed on the drugs should include all taxes and should be uniform everywhere.

Purchase of drugs by the Govt. takes place in various level and states. If the Govt. regulate the purchasing procedure centrally it provides very big bargaining power. The Govt. can reduce procurement price by directly bargaining with the industry. This kind of procedure has helped reducing prices of drugs in many countries. ■



