Access to
Essential Medicines

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First Edition :February, 2007

Developed & Published by:

National Coordination Committee, Jan Swasthya Abhiyan

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Printed at:

Progressive Printers, 21 Jhilmil Industrial Area, Shahdara, Delhi-110092

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- All India Drug Action Network (AIDAN)
- Asian Community Health Action Network (ACHAN)
- All India Democratic Women's Association (AIDWA)
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About the Jan Swasthya Abhiyan

In 1978 at Alma Ata, the governments of the world came together to sign the Alma Ata Declaration that promised "Health for All by 2000". However this promise was never taken very seriously and was subsequently marginalised in health policy discussions.

As the year 2000 approached it appeared that "Health for All by 2000" was quietly being forgotten by governments around the world. To remind people of this forgotten commitment the First People's Health Assembly was organised in Savar, Bangladesh in December 2000 . The People's Health Assembly was a coming together of people's movements and other non-government civil society organisations all over the world to reiterate the pledge for Health for All and to make governments take this promise seriously. The assembly also aimed to build global solidarity, and to bring together people's movements and organisations working to advance the people's health in the context of policies of globalisation.

The national networks and organisations that had come together to organize the National Health Assembly, decided to continue and develop this movement in the form of the Jan Swasthya Abhiyan (People's Health Movement). Jan Swasthya Abhiyan forms the Indian regional circle of the global People's Health Movement..

Despite medical advances and increasing average life expectancy, there is disturbing evidence of rising disparities in health status among people worldwide. Enduring poverty with all its facets and in addition, resurgence of communicable diseases including the HIV/AIDS epidemic, and weakening of public health systems is leading to reversal of previous health gains. This development is associated with widening gaps in income and shrinking access to social services, as well as persistent racial and gender imbalances. Traditional systems of knowledge and health are under threat.

These trends are to a large extent the result of the inequitable structure of the world economy, which has been further skewed by structural adjustment policies, the persistent indebtedness of the South, unfair world trade arrangements and uncontrolled financial speculation - all part of the rapid movement towards inequitable globalisation. In many countries, these problems are compounded by lack of coordination between governments and international agencies, and stagnant or declining public health budgets. Within the health sector, failure to implement primary health care policies as originally conceived has significantly aggravated the global health crisis. These deficiencies include:

- A retreat from the goal of providing comprehensive health care
- A failure to promote participation and genuine involvement of communities in their own health development.
- A lack of insight into the inter-sectoral nature of health problems and the failure to make health a priority in all sectors ofm society.
- A failure to promote participation and genuine involvement of communities in their own health development.

- Reduced state responsibility at all levels as a consequence of widespread and usually inequitable policies of privatisation of health services.
- A narrow, top-down, technology-oriented view of health and increasingly viewing health care as a commodity rather than as a human right.
- It is with this perspective that the organisations constituting the Jan Swasthya Abhiyan have come together to launch a movement, emerging from the Peoples Health Assembly process. Some objectives that this coalition set for itself (which are set out in detail in the Peoples Health Charter) can be listed briefly as below:
- The Jan Swasthya Abhiyan aims to draw public attention to the adverse impact of the policies of iniquitous globalisation on the health of Indian people, especially on the health of the poor.
- The Jan Swasthya Abhiyan aims to focus public attention on the passing of the year 2000 without the fulfillment of the 'Health for All by 2000 A.D.' pledge. This historic commitment needs to be renewed and taken forward, with the slogan 'Health for All - Now!' and in the form of the campaign to establish the Right to Health and Health Care as basic human rights. Health and equitable development need to be reestablished as priorities in local, national, international policy-making, with Primary Health Care as a major strategy for achieving these priorities.
- In India, globalisation's thrust for privatisation and retreat of the state with poor regulatory mechanisms has exacerbated the trends to commercialise medical care. Irrational, unethical and exploitative medical practices are flourishing and growing. The Jan Swasthya Abhiyan expresses the need to confront such commercialisation, while establishing minimum standards and rational treatment guidelines for health care.
- In the Indian context, top down, bureaucratic, fragmented techno-centric approaches to health care have created considerable wastage of scarce resources and have failed to deliver significant health improvements. The Jan Swasthya Abhiyan seeks to emphasize the urgent need to promote decentralisation of health care and build up integrated, comprehensive and participatory approaches to health care that places "Peoples Health in Peoples Hands".

The Jan Swasthya Abhiyan seeks to network with all those interested in promoting peoples' health. It seeks to unleash a wide variety of people's initiatives that would help the poor and the marginalised to organise and access better health care, while contributing to building long-term and sustainable solutions to health problems

The Jan Swasthya Abhiyan is being coordinated by National Coordination Committee consisting of 21 major all India networks of peoples movements and NGOs. This is the sixth book in a series brought out by the NCC for the NHA II.

Contents

Access to Essential Medicines

Section I
Rational Medical Care

Introduction

> "*The physician who fails to enter the body of the patient with the lamp of knowledge and understanding can never treat diseases rationally*"
> - Charaka (120-162 AD)

Indians spent over Rs.25,000 crores last year in buying drugs and perhaps a similar amount in paying for diagnostic and surgical services. This adds up to approx. Rs.40,000 crores — or, to put it in another way, Rs.2,000 for every family in the country. It has been estimated that at least 50% of this expenditure is incurred on irrational or unnecessary drugs and diagnostic tests or surgical procedures. This adds up to a colossal waste of Rs.15,000 - 20,000 crores every year, and amounts to an average unnecessary drain of Rs.1,000 per year for every family!

Unfortunately, *irrationality is like dowry - a social evil that is easy to detect, yet difficult to define in an individual case, perpetuated by human avarice, impossible to eradicate and if unchecked may have fatal consequences*. Like all social evils, multiple factors are responsible and all the key issues need to be addressed if a dent has to be made in irrational practices related to health care.

Irrational Prescribing

The first, and best known, part of irrational practices in health care is related to irrational prescription of drugs. **WHO has defined irrational prescribing as use of a therapeutic agent when the expected benefit is negligible or nil or when its usage is not worth the potential harm or the cost.**

Irrational drug prescribing can occur when the medication prescribed is incorrect, inappropriate, excessive, unnecessary or inadequate. Accordingly, the types of Irrational Prescribing are:

- **Incorrect prescribing**: This means the use of wrong medicines to treat a disease or the use of medicines when no medicines are required.
- **Inappropriate prescribing**: This pertains to use of medicines that are not suitable for the particular patient, viz. use of medicines that may be harmful in pregnancy, in children, in older people, etc.
- **Over prescribing**: This is related to use of too many different kinds of drugs to treat a disease, when fewer (or just one) drugs would have sufficed. It also includes use of drugs for long periods, when a shorter course of treatment is adequate.
- **Multiple prescribing**: This means the prescription of more than one drug of the same kind (i.e. drugs which have the same effect) to treat a disease
- **Under prescribing**: This has to do with prescribing medicines for too short a duration or in inadequate dosage.

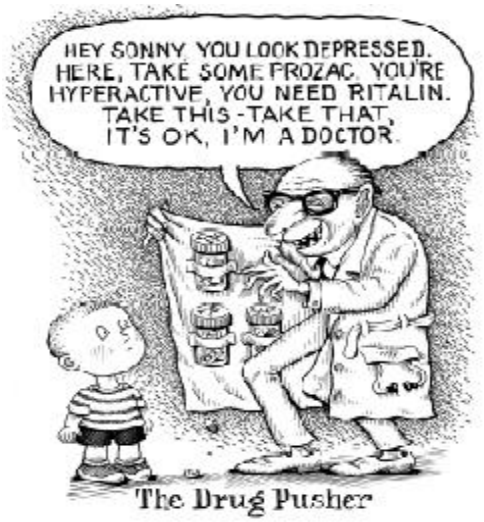
Proliferation of Irrational and Useless Drugs

All these irrational practices are rampant in India. The reasons are manifold. One is to do with the proliferation of a large number of drugs in the Indian market that are either irrational or useless. With rapid developments in Science and Technology there has been an explosion in the number of drugs which are available in the market. Unfortunately only a small minority of drugs entering the market offer an advantage over existing drugs. A study in the U.S. showed that of the 348 new drugs introduced from the 25 largest US drug companies between 1981 and 1988 : 3% made an "important potential contribution to existing therapies"; 13% made a "modest potential contribution; and 84% made "little or no potential contribution". A French study of 508 new chemical entities

marketed in the world between 1975 and 1984 found 70% offered no therapeutic improvement over existing products. The situation in India is no different and probably worse, given the fact that our Drug Control mechanisms are much more lax than in developed countries. The only reason why Indian studies are not available is because there is virtually no mechanism in India to monitor the use of irrational and hazardous drugs.

As a consequence there are an estimated 60,000 to 80,000 brands of various drugs available in the Indian market. On the other hand the WHO lists a little over 270 drugs which can take care of an overwhelming majority (over 95%) of the health problems of a country. In this situation of extreme anarchy the task of an already overstretched Drug Control Authority becomes almost impossible to cope with. A majority of the estimated 80,000 products in the market are either hazardous, or irrational or useless.

The pharmaceutical companies and the government regulatory bodies are both to blame for allowing such a situation to develop in this country. But all this would not be possible without the active involvement of the medical profession, who contribute by prescribing such irrational and useless drugs. One reason for this is the fact that there is almost no source of regular unbiased, authentic information on drugs available in the country. Given the rapid changes in treatment procedures and introduction of a large array of new drugs, medical practitioners need to update their knowledge regularly. Such a system of continuing medical education is largely absent in this country, and most doctors do not find the need to take time out from their busy practice to update their knowledge by reading the most recent books and journals. Thus we have the sad practice of a bulk of medical practitioners depending on promotional material supplied by Pharmaceutical companies. Obviously such promotional material only provides biased information to doctors, with a view to maximising the sale of the products being promoted. It thus makes it possible to sell a large number of useless and irrational drugs.



The Drug Pusher

Some common irrational or useless or hazardous drugs are mentioned below. It may be noted that this is just a short illustrative list, and there are numerous other examples available.

Analgin: The drug can cause agranulocytosis, a fatal blood disease. The drug can also cause rashes and serious life threatening cerebral coma. Large doses can cause renal tubular necrosis, a degenerative disease of the kidneys. In India Analgin is used in trivial cases and can be procured from most chemists without a prescription.

Clioquinol :Clioquinol belongs to a group of drugs called Halogenated Hydroxyquinolines. In the Sixties this drug was found responsible for a massive epidemic of a syndrome called SMON associated with progressive muscular weakness, degeneration of nerves and loss of vision. As a result the drug was banned in many countries and the original manufacturer Ciba Geigy, withdrew it from the world market. Yet in India it continues to be freely available under various brand names — like Enteroquinol.

Oral Rehydration Salts (ORS) : ORS is a combination of sodium chloride, sodium bicarbonate or trisodium citrate, potassium chloride and glucose in a fixed ratio. This solution is used to treat dehydration caused by acute diarrhoea, a condition that takes millions of lives (especially in children) every year in the Third World. The rational use of ORS, it is estimated by the UNICEF, is

today saving one million lives every year in the Third World. In spite of the extreme importance of this product, quality control norms for ORS are not rigorous in India. There are a large number of ORS brands available in the market which do not conform to the WHO formula. Most irrational ORS solutions available have low sodium content and high glucose content. But a high glucose solution actually worsens diarrhoea and a low salt soln. does not correct the sodium loss — the main cause of deaths due to dehydration. Such solutions thus can in fact not save lives but endanger them further. Yet even the Brand leader ELECTRAL, does not conform to the WHO formula.

Fixed Dose Combination: One of the major reasons for proliferation of drugs in the Indian market is the presence of a huge number of Fixed Dose Combinations that is a single Formulation containing 2 or more drugs in a fixed ratio. Most of these combinations are without any rationale except the motive to make profits. The WHO says in this context: "*In the great majority of cases essential drugs should be formulated as a single compound. Fixed-ratio combination products are acceptable only when the dosage of each ingredient meets the requirements of a defined population group and when the combination provides advantage over single compounds administered separately in therapeutic affect, safety and compliance*. (WHO Technical Report Series, 722.) The WHO list of essential drugs includes only 7 drugs in a total of 270 drugs.

All drugs may be called useful poisons. Fixed-dose combinations add an unnecessary load of adverse effects on the patient and in addition add to the cost of therapy - in the ultimate analysis they help no one but the drug manufacturers in most cases. Given this background there is necessity to critically examine and weed out all unnecessary combinations from the Indian market. This single step would considerably cut down the anarchy in the Indian Drug market. Some combination products which should be urgently weeded out include:

Irrational Cough Syrups: There are a large number of cough syrups available in the market, a majority of which are irrational. Many of these combine cough suppressants with expectorants (i.e. an ingredient which facilitates expulsion of sputum.) Moreover cough syrups are seldom effective in treating cough, and only in rare circumstances is their use justified. The British National Formulary says: *"The drawback of prescribing cough suppressant are rarely outweighed by the benefits of treatment and only occasionally are they useful as, for example, if sleep is disturbed by a dry cough. Cough suppressants may cause sputum retention and this may be harmful in patients with chronic bronchitis, etc.* Cough syrups, hence, are usually not only irrational in that they combine ingredients with opposing therapeutic aims, but it is doubtful whether the ingredients are capable of exerting the effect they are supposed to : that is as cough suppressants or as expectorants. Given this background, all cough mixtures need to be critically reviewed.

Combinations of Antibiotics: A large number of combinations of two different antibiotics are available in the market. Two categories of these are rational - combination of trimethoprim and sulphamethoxazole as co-trimoxazole and combination of anti T.B. drugs. These are the only two combinations mentioned in the WHO list of Essential drugs. Most other combinations carry the risks and disadvantages associated with combination products related earlier. In the case of antibiotics the disadvantages are greater, one because the side effects tend to be more pronounced; two because the increase in cost is greater; and three because of the added risk of developing antibiotic resistance. The commonest irrational combinations available is a combination of Cloxacillin with Amoxycillin or Ampicillin.

Other Combinations: Such s combinations of two or more pain-killers, combination of drugs that reduce acid secretion with drugs that stop vomiting, etc.

Prudent Use of Diagnostic Tests

Before requesting an investigation, the clinician should ask himself/herself the following queries:

Will the test result help me to:
Confirm/establish diagnosis,
Rule out a diagnosis,
Monitor therapy,
Estimate prognosis, or
Screen for and detect a disease?

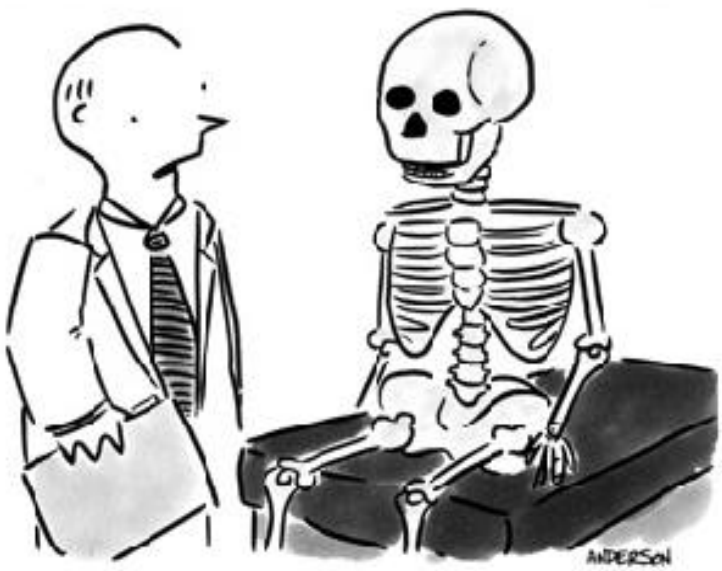
Can the abnormality I seek in this case:
Exist without any clinical evidence of it?
Even if present, be in any way harmful to the patient?
Be treated or controlled? and
Be worth the cost and the risk for this patient?

Is there no safer and more economical alternative?

If, after careful thought, the answer to all these questions is a clear 'No', then there is no need to do the test. If the answer to any one of them is 'Yes', the test may need to be performed depending on its availability, predictive values and affordability.

Irrational Prescribing

It needs to be understood that the problem is not limited to just a question of irrational or useless or harmful drugs. Rational, or even life saving drugs can be used in an irrational manner. The commonest problem is the unnecessary use of drugs. Thus, often we see expensive antibiotics being used for trivial infections. Moreover this is often accompanied by wrong dosage schedules. Another problem is the prescription of a large number of drugs for a simple ailment, when one or few drugs would have sufficed. Doctors, in many cases, when they are not sure of the diagnosis prescribe a large no. of drugs to cover for all the possibilities. Thus



"Still, let's do an x-ray just to be sure."

a patient coming with fever may be given some antibiotic, a drug to treat malaria, a drug to treat typhoid, etc. It may turn out that the patient was just suffering from a viral fever, which could have been treated with some paracetamol tablets, only. Such prescription practices increase the cost to the patient, unnecessarily exposes the patient to potential side effects, and in the case of antibiotics leads to drug resistance, i.e. a situation when these antibiotics become useless when they are really required.

Patients must also realise that if a Doctor advises no drugs, he is giving as valuable (or in some cases more) advice as someone who prescribes a large number of drugs. All illnesses do not require drugs — in fact a large number of illnesses are "self limiting", i.e. the body cures itself without the use of drugs.

Rational Use Of Diagnostics

Using WHO definition of irrational drug therapy as the basis, irrational use of diagnostics (including laboratory tests of blood, urine, sputum, etc.; X-Rays; scans; etc.) may be defined as: "a diagnostic test is irrationally used when the expected benefit is negligible or nil or when it is not worth the potential harm or the cost."

While there is some awareness about irrational drug usage, almost no enough attention has been focused on irrational use of diagnostics. If one realises that an irrational CT-Scan is equivalent to about 100 bottles of an irrational 'tonic', then the importance of rational use of diagnostics will be apparent. One reason for this neglect may be that most medical professionals are not aware of the need to selectively and critically use the diagnostic tests and avoid the "tar baby syndrome".

Twelve Questions on Risk, Cost and Benefit

If you want to be an informed seeker of health care, discuss with the doctor the following points before agreeing to undergo any procedure.

1. What is actually wrong with me?
2. How serious is this disease/condition?
3. What may happen to me if I leave it untreated?
4. What kind of procedure are you planning to do?
5. Is the procedure done for diagnosis, for treatment or for both?
6. What are the risks of this procedure?
7. What are the chances that the proposed procedure will be successful in my case?
8. Will the success be a long term or short-term benefit?
9. What alternative procedures/treatments are available?
10. Of these, which do you think would be the best for me?
11. If your relative were in my position, what would you choose for him/her?

(If there is a difference between 10 and 11), please explain why?

12. Could you suggest any source of information on this disease that I could read or watch?

Monetary Compulsion lead to Irrational Practices

Bernard Shaw had an uncanny insight into the working of doctors' minds when faced with the dilemma of choosing between ethics and monetary compulsions. In 1906 he wrote thus in the preface to a piece called *"Doctor's Dilemma"*:

> "As to the honour and conscience of doctors, they have as much as any other class of men, no more and no less. And what other men dare pretend to be impartial when they have a strong pecuniary interest on one side?"
>
> "It is simply unscientific to allege or believe that doctors do not under existing circumstances perform unnecessary operations and manufacture and prolong lucrative illnesses."

Doctors in the private sector argue, "The patient is happy getting the maximum attention, we are happy collecting our fees and the health care industry is happy generating income and wealth for the shareholders. *It is an all-win situation*." This is a vicious argument and can attract the reply, "A drug dealer or a pimp will also use the same logic and say it is an all-win situation. Can you or society accept it then?"

The harsh reality is that two-thirds of our rural families are in debt because of health care expenditure. If the chain of rural indebtedness has to be broken, planners and health activists have to squarely address this issue and find some lasting solutions. For the conscientious doctor, there is an ethical self test that can be used as a guide: "Would I like myself or my near and dear to be treated thus?"

Eight Tips to Detect an Uncaring (irrational) Doctor

The following are some warning signs that indicate that your doctor may not be doing his/her best to help you.He/She:

1. Does not listen to what you are saying.
2. Does not probe into your symptoms and complaints.
3. Does not examine you completely or forgets to examine the organ or body system about which you have raised some doubts.
4. Seems to be forgetful and peculiar in behaviour, either smiles inappropriately or is short-tempered.
5. Acts in a paternalistic (fatherly) manner; is all-knowing and tells you "the only way" to manage your problem.
6. Does not educate you on the nature of illness and the rationale of tests ordered and treatment advised.
7. Does not discuss risks and benefits of the tests, procedures and medicines advised.
8. Gets upset or reacts defensively when you suggest seeking a second opinion.

   It is better to change to a more helpful doctor!

Case Dumping and Case Grabbing Erode Rationality

For-profit hospitals engage health care workers, transport workers and others as touts to fetch cases for surgery and other procedures. These touts can be spotted in and around other hospitals offering unsolicited "helpful advice" to prospective clients. Doctors in the know, working in the private sector say, "Cases admitted for surgery are discharged against medical advice and transferred to another hospital. Insiders are involved and get a good commission for doing this."

If case grabbing is rampant in private sector hospitals, case dumping is equally rampant into the public sector hospitals. In USA, over 250,000 emergencies were shifted from 'for profit' hospitals to public hospitals because they cannot pay. About one in ten, i.e., 25,000 cases die, mostly due to delay in transit (reported

in the Lancet 1991; 337: 38). In India, the situation of patient dumping is far worse.

Gullibility Promotes Quackery and Fraud

The dividing line between trust and gullibility is a fine one. When some one is ill, there is pressure to "do something" and it may be tempting to try unproven remedies. Health care quackery is big business even in the developed countries. Unethical advertising, uncritical media hype and human gullibility help propagate it. When the truth about "the miraculous cure" becomes apparent, the stakeholder shifts the focus to protect the health care business interests.

"The capacity of human beings for self-delusion should never be underestimated; conviction profoundly affects observation. If you think you are right and can convince the patient that you are right, then whether you are right or not makes very little difference" (R. Asher: Talking Sense. Pitman Medical Publishers, 1972).

Informed and enlightened consumers should break the shackles of age-old myths and superstitions. Health and consumer activists have another area that needs urgent intervention to prevent exploitation of the gullible. Some tips are listed below.

How do quacks succeed?

Over 90% of illness are self-limiting and the body heals itself. (Even 90% of snake bites are non-venomous and a quack can claim credit for its "cure" if he is smart enough to refer the minority with venomous bites).

Of the various factors that contribute to healing, only 20% is ascribed to rational treatment using medicines or surgery. The remaining 80% is divided among the following:

a) faith in a placebo (inactive substance or irrational procedures).
b) faith in a system, a facility or a professional
c) faith in self or in supernatural

If a clever quack learns to operate within these three faith-related areas and stay away from rational therapy, he/she can be quite successful with a majority of his clients.

Ten Tips to Detect possible Quackery or Fraud

Like politics, health care has also become the last refuge for many scoundrels. J.H. Young, a professor of history has compiled the following guidelines:

1. Exploitation of fear and phobias or of hope for a miracle.
2. Claims of miraculous scientific breakthrough
3. Promise of painless safe treatment with excellent chances of "cure".
4. Reliance on anecdotes and testimonials. They don't separate facts from opinions or cause and effect from a mere coincidence.
5. Heavy promotion by advertising.
6. Large sums of money payable by clients for achieving cure.
7. The use of Simpleton science (one-size-fits-all type of dogma): diseases have one basic cause and one way of treatment takes care of all diseases. For example, water is the basis of all diseases and hydrotherapy cures them.
8. The 'victim of scientific establishment' theory: "the establishment is blind, I am far ahead of times and will be a hero to future generations".
9. Shifting theory to adjust to changing circumstances.
10. Distortion of "freedom of informed choice" to "freedom of choice" to end up with "freedom to be foolish".

Holistic Care Promotes Rationality

"Holistic is a buzz-word today - different persons interpret it in different ways. It is not a mix and match of various systems of medicine as being interpreted now. Ancient physicians like Hippocrates and Charaka have advocated truly holistic perspective in medicine.

Hippocrates said "*I would like to know what kind of person has a disease rather than what disease that person has*. Just think about it! Even today, it is difficult to improve upon this simple and yet accurate view of holistic perspective. Consider the diseased person as a whole - his/her personality, attitude to life, knowledge, and socio-economic and cultural standing etc.- in order to understand the illness from a holistic viewpoint.

If Medicine had such a 'holistic' view, then when and how did it degenerate to be a dehumanised profession? As medical sciences advanced, we could understand more and more about the causation of diseases - revolutionary discoveries and progress were made in the field of medicine and therapy.

Our attention shifted more and more to the biological sciences at the expense of behavioural sciences. In order to cope up with the advances, specialisation became order of the day. As a cynic had said it, "Specialist doctors learn more and more about less and less until they know *everything about nothing*". Dr. K. White has coined the term *Ignorant Savant* for this breed of specialist doctors who are well informed in their own limited fields but are ignorant of patients life-world. T.S. Eliot lamented thus: "Where is the knowledge we have lost in information? Where is the wisdom we have lost in knowledge?"

Primary Care Can Promote Holistic Care

Just as stomach and bowels have a primary non-glamorous job of breaking down complex food, primary care provider has to have a holistic view of a patient's illness and sort out his/her various problems. Sorted out health problems have to be specifically referred for specialised treatment.

During the 70's and 80's, USA went for specialist treatment in a big way. It was a disease oriented, procedural, piece-meal approach that was ruinously expensive and soon controlled by insurance industry. Now the society has realised its folly and is reverting back to a primary care approach that is patient-oriented, holistic, continuous and comprehensive. Unfortunately, the third

world countries are caught in this quick sand now. Empowering "just an MBBS doctor" to shed his/her diffidence and practice rational primary care will go a long way to rectify the depressing scenario.

Primary care physicians need to develop into "health care advocates" for their patients. They must reverse the current trend and help patients to avoid inappropriate entry to specialist care; not merely because it is costly, but because it wastes everybody's time, incurs unnecessary risks and diverts attention from rational, more appropriate and effective solution (Hart JT: Lancet 1992; 340: 772-775).

The bottom line is not profit or high technology but rational care based on provider-seeker trust. If the basic trust is undermined, as has happened in the USA, the health care system will be in jeopardy and every player will be a loser. Trust is the glue that keeps the system together. Without that, it will fall apart like Humpty Dumpty and we may not be able to put it together again.

Section II
Drug Industry in India

Self Reliant Production of Medicines

While there has been a large overall growth in new drugs produced to treat diseases and their production globally, technology to produce these drugs is available only in a few countries in Europe, North America and Japan. Very few developing countries have access to technology to produce drugs and are dependent on Multinational Drug Corporations for drug production. This means that the poorest countries of the world have to pay high costs for drugs as they are at the mercy of MNCs.

India is a major exception to this and is the largest producer of drugs in the developing world. Today India produces 8% of all drugs in the world and is the Fourth largest drug producer in the world. Not only that, Indian drugs are exported – often at $1/10^{th}$ or less of the cost charged by MNCs – to over 200 countries. India, thus, is also a major source for cheap drugs for a large number of countries in Asia, Africa and Latin America.

India's success story did not happen by accident. At the time of independence, India was solely dependent on import and had very little domestic manufacture. But after the 1970s India developed capability to manufacture most essential medicines. This happened because at that time the Indian Government took a number of steps that promoted indigenous manufacture of drugs. Some of the majpr contributory factors include:

- Enactment of Indian Patents Act 1970.
- Changes in the Foreign Exchange Regulation Act.
- Introduction of new Drug Policy 1978.
- Establishment of large pharmaceutical public sector manufacturing factories like, Hindustan Antibiotics (HAL) and Indian Drugs and Pharmaceutical Limited (IDPL)

Table: Introduction of New Medicines in India

Medicine	Year of Introduction Globally	Year of Introduction in India
Salbutamol	1973	1976
Mebendazole	1974	1976
Rifampicin	1974	1980
Cimetadin	1976	1981
Bromhexin	1976	1982
Naproxen	1978	1982
Captopril	1981	1985
Norfloxacin	1984	1988
Ranitidine	1983	1985
Acyclovir	1985	1988
Ciprofloxacin	1985	1989
Astemizole	1986	1988

(Source: Conquest by Patent: TRIPS Agreement on Patent Laws; B. K. Keayla)

The Indian Patents Act of 1970, did not allow Patents on products. This meant that a chemical used for producing medicines could not be patented. As a result, Indian companies were able to produce and sell new medicines within 3 years of their being first marketed in the world market, and did not have to wait for 10-12 years for the Patent to expire. The following Table gives an indication as to how this helped introduction of new drugs in India within a short period after their global launch.

The introduction of new drugs was helped immensely by the efforts of Government research institutions like Central Drug Research Institute, Lucknow; National Chemical Laboratory, Pune, etc. They invented new processes for production of nearly all essential medicines. This allowed Indian drug companies to produce new medicines, even when they were patented in other parts of the world. Over a period these companies built a large manufacturing base in the country.

In addition, changes in the Foreign Exchange Regulatory Act (FERA) and the Drug Policy 1978 also contributed in forcing MNCs

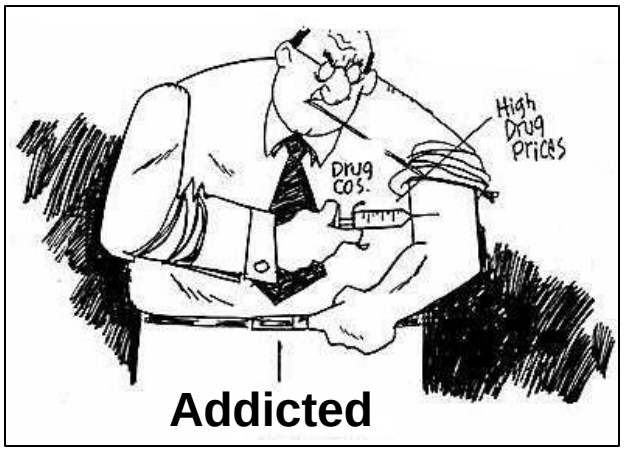
to start production in the country (earlier MNCs would just import the drugs at very high costs), and also allowed Indian companies to compete effectively with them. For example, the 1978 Policy stipulated ratio parameters, i.e. required that all drug manufacturers should also produce bulk drugs, thereby encouraging basic drug production in the country. Production bulk drugs jumped up from Rs.90 crores in 1974 to Rs.200 crores in 1978, and increased further to Rs.308 crores in the next five years.

The above developments led to a sharp drop in drug prices in the country after the 1970s. The prices of many essential medicines dropped to just $1/8^{th}$ to $1/10^{th}$ of the earlier prices. Unfortunately many of these trends were not sustained as neoliberal economic reforms had an impact on policies related to the manufacture and pricing of medicines as well.

Contribution of the Public Sector

The first public sector drug company – Hindustan Antibiotics Ltd. (HAL) — was set up in 1954 with the help of technology from the World Health Organisation (WHO) and the UNICEF. Later, with the help of technology from the Soviet Union, a much larger public sector investment was made in establishing the Indian Drugs and Pharmaceuticals Limited (IDPL) in 1961 at Rishikesh, Hyderabad and Chennai. IDPL started production of 16 bulk drugs and 166 types of surgical instruments. These two public sector companies was able to supply nearly 70 percent of bulk drugs needed for the country – a role they performed till the late 1980s. In fact, at the time of establishment, the IDPL plant at Rishikesh was the largest single pharmaceutical unit in Asia.

Public Sector companies were the first to start significant production of basic medicines in India. This forced MNCs to also start production, and subsequently a large number of Indian companies in the private sector also commenced manufacturing. The public sector medicine companies produced quality medicines in large quantities at a much lower price, which compelled the multinational companies to sell their medicines at a much lower



price than earlier. Public sector companies also supplied many bulk drugs to the small scale sector and the market competition brought down drug prices further.

We have already talked about the important role played by research institutions in the public sector, like CDRI and NCL. Almost all big pharmaceutical companies in our country have benefited from the research conducted in these laboratories.

MNCs start Closing Down Factories

The huge gains of the 1970s and 1980s that improved access to medicines could not be sustained. A major reason for this was the impact of economic reforms in India from the early 1990s. The regulatory control on the pharmaceutical industry was virtually abandoned. With the signing of the WTO agreement in 1994, India's 1970 Patent Act also required to be changed. The earlier policy that required companies to manufacture in the country was abandoned. As a result MNCs soon reversed their earlier initiatives to produce drugs in the country. They started shutting down their manufacturing units, and concentrated on selling drugs formulated from imported bulk drugs or from the small scale sector. Thus, from an industry engaged in basic manufacturing, there is now a transition towards large companies becoming traders. While the trend was set by MNCs, Indian companies too have become part of this trend. The effect is clearly visible if one were to visit the Thane

– Belapur area near Mumbai, once considered the heart of drug manufacturing in India. Today, the area looks like junkyard and the area is fast being converted, by real estate developers, into housing complexes and shopping malls.

At present, only 5-6 MNCs have retained production units in India. The rest either import the medicines that they sell or get their medicines in the small scale sector. These MNCS, thus maintain a huge presence in the Indian market without manufacturing anything themselves. For example the largest drug MNC in the world Glaxo Smith Kline — had factories spread across India — right from Mumbai, Thane, Gujarat, Bangalore, Nasik to Aligarh, Most of these factories have now been closed down, yet the company sold medicines worth over Rs.1,000 crores in 2004. Clearly, MNCs now see an opportunity in the changed laws to lay off their work force and shift the production of medicines to small sale sectors to utilize less taxes and production costs.

We have seen how relaxation of controls by the Government has allowed MNCs to depend heaviy on imported drugs once again. The recent change in the Indian Patents Act, removing the feature of the 1970 Act that did not allow Patents on medicines, will also allow MNCs to import high priced patented medicines directly without facing competition from Indian manufacturers. We already see a trend of rising imports.

Since the country signed the WTO agreement, imports of finished formulations have surged from Rs.173 crore to Rs.680 crore in 1999-2000 and Rs.900 crore during the first three quarters of the current financial year. This is an increase of a whopping 420 per cent, and as the year concludes, the rate of increase would be registered as 500 per cent or more.

Medicines which have been recently introduced in the global market are another cause for concern. These medicines are under patent protection, and extremely expensive. Many of them do not actually have additional therapeutic advantages over existing medicines. Major multinational drug companies have now begun pushing new drugs with an unprecedented zeal. As the existing price

regulation mechanism doesn't cover imported drugs, the MNCs are flooding the market with prohibitively priced monopoly products. The absence of an import duty differential on basic chemicals, intermediates and bulk drugs with the finished products, contributes to the trend.

Multinationals are largest importers

Novartis's brands of immuno-suppresant drug, cyclosporin has recoded a turnover of Rs.40 crore in less than year of its introduction in the Indian market. The cost of the drug to the consumer is as high as Rs 1,000 to Rs 3,000 a month, and the treatment duration is normally one to two years, clearly indicating that the drug is meant for the high-end market.

Similarly, Eli Lilly has introduced its cardiovascular product Reobro, a branded version of Abxicimab. Reobro has already recorded a turnover of over Rs.40 crore in India. A full course of Reobro costs Rs.30,000 to 50,000 a month.

Shifts in Pharmaceutical Policy

Hathi Committee and After

In 1974 the Indian Govt. set up the Committee on the Drugs and Pharmaceuticals Industry (popularly known as the Hathi Committee). The Committee's recommendations were seen by many as a landmark for drug manufacture in the third world. Countries like Bangladesh and Sri Lanka were to borrow heavily from it. The Drug Policy of 1978 and the Drug Price Control Order (DPCO) 1979, were broadly based on recommendations of the Hathi Committee. Following the recommendations of the Hathi Committee the Drug Policy, 1978 announced certain measures towards self reliance in medicine production in the country. Important policy stipulations are as follows.

- Priority to public sector companies
- Reservation of certain medicines for production by public sector companies

- Fixed ratio of production of bulk drugs to formulation to compel multinational medicine companies to produce more bulk drugs
- Compulsion for use of medicines in generic names
- Exemption of small scale producers from certain taxes
- Stronger licensing system to restrict multinational companies in simple formulation preparation
- Multinational companies should bring down their foreign share holdings to below 40 percent

Following this policy the Govt. also declared a Drug Prices Control Order, 1979 (DPCO) bringing nearly 378 medicines under price control. The Govt. also formed a National Drugs and Pharmaceuticals Development Council (NDPDC) to monitor the implementation of the Drug Policy. The 1978 Drug Policy helped the Indian drug companies to grow at a fast pace. It reversed the earlier situation where the Indian market was dominated by MNCs (see Table).

But in 1986 the Government, in a new Policy, reversed many positive features of the 1978 Policy. The span of price controls was reduced, greater profitability was allowed, imports were liberalised and various production control measures were scrapped. In 1994, the government announced its new policy on Drugs and Pharmaceuticals. While continuing the trend set in 1986, the Govt. reversed all positive features of the 1978 policy which had helped to built a self reliant industry, the best of its kind in the third world, and comparable to those in many developed countries. In the new policy the Govt. granted major concessions to the industry in terms of reduced price

Tabel: Share of Medicine Market in India

Year	MNCs %	Indian Cos. %
1952	38	62
1970	68	32
1978	60	40
1980	50	50
1991	40	60
1998	32	68
2004	23	77
2005	20	80

(Source: ORG MAT, Several issues)

and production controls. They included the slashing down of the number of drugs under price control and increase in returns allowed for drug manufacture.

The Government's pious hope that market forces will work to keep prices of drugs stable was belied and the country witnessed a spiralling rise in Drug Prices since the 1994 policy.

Drug Policy 2002 and After

The Drug Policies enacted by the Government in 1986 and 1994 saw a dilution of virtually all the beneficial measures of the 1978 Drug Policy. By the time the Pharmaceutical Policy,2002 was declared the public sector medicine companies were almost killed. IDPL remain closed since 1996 and HAL was facing a staggering loss needing infusion of capital form the Govt. All reservation for production for the public sector was withdrawn.

This 2002 policy abolished all licensing restrictions and allowed 100% foreign share on investment. The Govt had doubled the excise duty from 8% to 16% for medicines, which enhanced the prices of domestic production. At the same time it liberalised imports and cut import duties – thus making it more lucrative to import medicines. The policy also recommended for total abolition of the Drug Price Control Order (DPCO) in stages. Thus all control over the medicine sector was virtually withdrawn. Repercussion of such wholesale withdrawal of regulatory control in this sector led to increase of import, spiralling rise of drug prices and flooding of the market by high priced imported medicines.

Table: Drugs Under Price Control

Policy	No. of Drugs under Price Control
1978	378
1986	166
1994	74
2002	25-30*

** Not implemented due to stay order by court*

The Govt. in tune with the industry's claim that price control is counter productive to the availability of medicines, declared that control on prices of medicines will be fully withdrawn gradually. Though termed as a "Drug Policy",

the new changes were only aimed at allowing a rise in drug prices. The New Policy immediately reduced the number of drugs under Price Control to just 38. Thus, in one sweep, the volume of pharmaceuticals under price control was reduced from an estimated 40% to just 25% of the total drug market. There was no attempt to provide even the semblance of justification for the decontrol of drug prices. Fortunately this recommendation was not implemented because of a Court Order, because of a Public Interest Litigation (PIL) filed by consumer groups. Subsequently the Court stayed the Government's decision to slash price controls and directed that price controls be imposed on all Essential medicines.

Following this the present Government circulated a draft "National Pharmaceutical Policy – 2006". Though the new draft does not address many key issues of public health it does mention the Government's desire to control prices of medicines required for national programmes (47 drugs) and all drugs under the national essential drug list (354 drugs). This is a welcome decision but is now facing challenge from the industry and even Government Departments like Finance. As a result the new policy is yet to be finalised.

Who Makes Medicines?

According to the Director General of Trade and Development (DGTD) register there are 25,000 drug manufacturing units in India – including large and medium sized Indian companies, MNcs (about 40) and companies in the Small Scale Sector. In reality, more than half of these have no manufacturing facilities. It is difficult to get a true picture regarding how many really exist as the DGTD does not maintain a live register.

Till the early 1960s, i.e. before Indian companies commenced drug production, MNCs would claim that Indian companies do not have the competence to manufacture medicines. This was shown to be a hollow claim when public sector units like HAL and IDPL started producing quality drugs in the country. This was followed by the setting up of manufacturing units by Indian companies,

including even a large number in the Small Scale Sector. The story has now come a full circle. Barring a few, most MNCs have no production units in India. Many of them have sold their well-known brands to Indian companies. In fact, most of the drugs sold by the MNCs directly are now being produced in the small scale sector.

The Real Manufacturers!

One of the top-selling medicines in India is Becosules, an irrational combination of Vitamins that is marketed by Pfizer. We examined the label of Becosules, and found mentioned that the medicine is manufactured by Pfizer at Compartment No.52, Plot No.52 Marol Industrial Estate, Mumbai-400059. On visiting the address we could not find out even a sign board of M/s Pfizer Ltd. The address is of a small company, who actually manufacture Becosules and label it as Pfizer's product. An allied issue also is: in case of any complaints regarding quality, who would be responsible?

A close observation of the labels of well known brands of large companies would show that many are not produced by the "reputed" company that owns the brand. Typically they provide the raw materials, and based on these the drug is formulated and packaged with the company's label by a small manufacturing unit. In such cases the real manufacturer is mentioned in tiny letters on the package, designed to be overlooked by the consumer, while the "reputed" company's name and brand are both printed in large bold letters. Some large companies utilise the services of 10-15 small manufactures to produce different brands sold by them!

Large companies claim that their quality is superior and they use this argument to justify the higher prices (at times 10 times more than another brand!) they charge for their products. It is a moot point how they can claim so given that often their own drugs are manufactured by small companies while they themselves act as mere traders and do not control the manufacturing or quality. Thus the belief that big companies produce quality medicines is often a huge myth.

Prices of Medicines

In a country like India where a majority of the people are poor, the prices of medicines determine access. According to *The World Medicines Situation* (WHO 2004): "In 1975, less than half the world's population were estimated to have regular access to essential medicines. New estimates from the 1999 World Medicines Survey show that this fraction has fallen to around one third. However absolute number of people without access has remained unchanged, at about 1.7 billion. Getting the right medicines to the people who need them at the time they need them remains a major challenge." The same publication mentions that **in India 56% of the people have no access to modern medicines.**

Clearly, control of drug prices is vital if access of essential drugs is to be ensured. In 1970 the prices of all medicines were controlled by the Government. The 1979 Drug Price Control (DPCO) order retained 378 medicines under price control. Profit margins of controlled drugs were kept at 40% (for life saving drugs), 55% (for essential drugs) and 75% (for others). The 1979 DPCO was strongly opposed by the industry, led by MNCs who then controlled a bulk of the Indian market for medicines. They even challenged the order in court and when this failed, they stopped production of essential drugs that were under price control. multinational companies went to court against it and stopped production of many essential medicines under price control. Subsequent investigations brought to light several cases of over charging by MNCs, in blatant violation of the Government's order.

Unfortunately, the Government finally succumbed to the pressure from drug companies and the Drug Policy of 1986 decreased the number of drugs under price control from 378 to 166 and increased the profits allowed to 75% and 100%. Further concessions were made in the 1994 policy when the number of price controlled drugs were reduced to just 74. As discussed earlier the 2002 Drug Policy made the situation even worse. So in a period of 20 years the efforts at drug price control have been effectively

Table: Variation of Prices of same Medicine in different Brands

Medicine	Brand	Company	Price	Difference
Ofloxacin 200mg	ZO Tarivid	FDC Aventis	3.20 31.00	969%
Levofloxacin 500mg	Levoflox Tavanic	Cipla Aventis	6.82 95.00	1392%
Azithromycin 250mg	Zathrin Vicon	FDC Pfizer	8.50 13.14	60%
Zidovudin 100mg	Zidovir Retrovir	Cipla GSK	7.70 53.52	695%
Amlodipin 5mg	Amlodac Amlogard	Zidus Pfizer	1.51 6.00	397%
Glimipiride 1mg	Glimister Amaryl	Mankind Aventis	0.80 5.30	696%
Pioglitazone 1mg	PIO Piozone	Systopic Nicholas	0.99 6.00	606%
Atenolol 50mg	Zibloc Tenormin	FDC Nicholas	0.40 2.45	612%
Letrozole 10mg	Onolet Femera	Biochem Novartis	9.90 181.50	1833%
Resperidone 2mg	Respidon Risperdal	Torrent Ethnor	1.69 27.00	1589%
Sildenafil 100mg	Penegra Viagra	Zydus Pfizer	29.16 584	2002%

Source: Compiled by A. Bhargava and C. Srinivasan

dismantled. **This has led to progressive and spiralling rise of drug prices.**

With most drugs out of price control, companies are able to charge what they want. The following table shows how the price of the same drug varies widely, when manufactured by different com-

panies. At times this varation is up to 500%! One can imagine the huge amounts of profits that companies are able to make.

The following Table gives examples of prices of some pain killers. The Table illustrates how companies make further super profits through irrational combinations such as above. While Runac costs Rs.6.00 for 10 tablets, its price is increases to Rs.12.00 after adding Paracetamol that sells at Rs.3.00 in the market. Similarly, simply adding Rabiprazol in Safediclo increases the price of Diclofenac four fold over plain Dichlofenac. There are many such examples, and they show why there is a proliferation of a large number of irrational combinations – the effort is to make even higher profits through them.

Table: Prices of selected pain killers (in Rs for 10)

Brand	Composition & pack	Company	Price
Dispirin	327 mg Aspirin	Reckit Colman	3.00
Ecospirin	320 mg Apirin	USV	10.50
Fenside SR	100 mg Diclofenac	Nicholas	12.00
Safediclo	100 mg Diclofenac + Rabiprazole	Nicholas	43.25
Runac	50 mg Diclofenac	Sun Pharma	6.00
Runac P	50 mg Dichlofenac + 500mg Paracetamol	Sun Pharma	12.00
Ibugesic	200 mg Ibuprofen	Cipla	3.25
Ibugesic Plus	200 mg Ibuprofen + 327 mg Paracetamol	Cipla	7.41
Emulide	100 mg Nimesulide	Emcure	12.50
Emulide-P	100 mg Nimesulide + 325 mg Paracetamol	Emcure	23.50

Myth of Low Prices

There is a prevailing myth that drug prices in India are the lowest in the world. This is at best a partial truth. Drugs that are still Patent Protected are much cheaper in India due to India's earlier Patent Act. It should be obvious that we would lose this advantage after amendment of the Indian Patent Act of 1970. But off-Patent Drugs (which anyway account for 80-85% of current sales in the country) are not necessarily cheaper in India. In fact, generally, Drug prices for these Drugs are higher in India than those in Sri Lanka and Bangladesh. In fact prices of some top selling drugs are higher in India than those in Canada and the U.K. The above shows that the advantage that the Indian Pharmaceutical Industry enjoys over other developing countries, in terms of the availability of indigenous technology and a large domestic market, have not been passed on to the consumers.

Drug Price Control is a Global Phenomenon

It is important to underline that drug prices are controlled by differing mechanisms all over the world, including in developed capitalist countries. In Australia since 1993, new drugs with no advantage over existing products are offered at the same price. Where clinical trials show superiority, incremental cost effectiveness is assessed to determine whether a product represents value for money at the price sought. In Britain, there exists the pharmaceutical price regulation scheme — a voluntary agreement between Britain's Department of Health and the Association of the British Pharmaceutical Industry in which companies negotiate profit rates from sales of drugs to the National Health Scheme.

Globally, Drug Companies are being forced to reduce the cost of medicines. Pressure is being mounted by Health Insurance Cos., Health Management Organisations (HMOs) and Governments (in countries like U.K. and Canada where the State provides Health Insurance cover) all over Europe and North America. These pressures have become stronger in recent years with the realisation

from the global experience that market mechanisms cannot be expected to stabilise prices. Various other interventions are needed to manipulate the market, in order to guard against monopolies emerging. Unlike in the case of consumer goods, there is no direct relation between the market and consumers in the case of drugs. Drugs are purchased by consumers on the advice of doctors or chemists. Consequently, the marketing strategies of drug companies target doctors or chemists. Doctors are not known to take decisions based on price of contending brands. Similarly chemists have no interest in selling cheaper brands. So, if we believe that drug prices will be kept low by market competition, it is a belief that is not borne out by the past experience, in India or elsewhere.

Unethical Marketing practices

The Indian market for medicines is flooded with irrational medicines and medicines of dubious value. Many of these medicines have a huge market. An obvious question would be: how do these medicines the sold if they are of little or no value in treating illnesses? Rational and essential medicines have a ready market and extra efforts do not need to be made to generate a demand for

such medicines. But medicines with little or no therapeutic use require special efforts to create a market for them. This is where the role of unethical marketing practices is seen – practices that create an artificial demand for useless products.

The drug industry in India spends 20% of its annual sale amounting to Rs.4,000 crores in advertising. This works out to about Rs.50,000 per doctor per annum and each doctor prescribes drugs worth Rs.250,000 per annum. Irrational use of diagnostics are maintained by a well established kick-back scheme all over India. It is of great concern that what started in Mumbai in the 70s has spread throughout the country and is the most important cause for unnecessary health care interventions.

In our country one can establish a medicine company without developing any manufacturing unit but every company has to maintain an elaborate marketing department. Drug companies spend huge amounts on "gifts" and other "incentives" directed at the medical profession. They use false or misleading evidence to promote irrational medicines. In promotional literature used by drug companies, claims for efficacy are not backed by scientific evidence and extraordinary claims are maid to confuse the medical profession. Doctors are often lured into prescribing a company's products through gifts ranging from toothpicks to car! They are also sponsored to go for foreign jaunts or to jaunts in exotic locations in India.

Such practices not only have a corrupting influence on the medical profession but also contribute greatly to the proliferation of irrational medicines in the market and induce irrational prescriptions. The situation is compounded by the fact that there is no clear source for unbiased drug information to the country, and doctors often depend on drug companies to obtain information about new products.

Many countries have systems in place that control the kind of information that companies provide, about their products. A model guideline for promotion of medicines is available with the World Health Organisation (WHO), which provide ethical criteria for

marketing of medicines. In our country, in absence of any criteria being laid down by the Government, drug companies are free to do as they wish. A visit to a busy doctor's clinic would often show large quantities of expensive promotional material, gifts, samples of drugs – testimony to the colossal waste of resources because of aggressive promotional tactics of drug companies. Ultimately consumers end up in paying for this wasteful expenditure, in the form of higher prices for medicines. Clearly, there is a need for strict regulation of drug promotion.

Why Do We Need a Drug Industry?

Finally, we need to understand that drugs are a commodity that are required most crucially by those who are least likely to be able to pay for them. Unlike commodities like cars or washing machines, the whole logic for the existence of the Industry lies in its ability to provide its products to the people who are economically deprived. If the Industry fails in this fundamental endeavour, the very reason for its existence is open to question. We already have a situation where a majority of our population does not have access to drugs, because they cannot afford to pay for them. In such a situation rise in drug prices can only "cost out" larger sections of the population. It can then legitimately be asked, if those who require drugs the most are going to be unable to afford drugs, why have a drug industry at all? The industry argues that adequate competition, even in the absence of price controls, can peg down drug prices. If that is so, why are they afraid of price controls?

Case Study of Availability Of Essential Drugs in Maharashtra in Public Health Facilties

What are Essential Drugs?

They are drugs which can fulfill the majority of the needs of a population (WHO). They number about 350 out of 2000 drugs that are currently used. Basic things to know about essential drugs:

- Must be available at all times in adequate quantities in the relevant health care centres.
- Unavailability of EDs can cause death or serious complications, which may lead to long-term impairment of health.
- Hence availability of EDs is a human right

Availability of Essential Drugs in in India

- In India per capita availability has increased from Rs.4.00 in 1948 to Rs.300 in 2003
- If we discount price rise, this rise is a mere two fold.
- A study in Satara district, (Maharashtra): **In 1991-92 if the per capita annual availability of Rs.100.00 were to be rationally and equitably used, all the drug-needs of the people for Primary level care would have been met.**

Poor Availability in the Public Sector

- About 30% of morbidities are left unattended due to poverty
- The proportion of Central govt's expenditure on health care as proportion of GDP, reduced from 1.3% to 0.9% during 1985 to 2003, while the WHO recommendation has been 5%
- Maharashtra Govt.'s health- expenditure declined from 1% to 0.6% of State Domestic Product, during 1985-86 to 2002-03.

As seen in a study in Satara district (1992-93):

- The drug-supply to the public sector in Satara District during 1991-92 was a mere 2.54% of the total drug supply to the district
- Nearly 60% of the drugs supplied to the PHCs were not available for more than 75% of the days of the year

Drug supply in The Municipal Corporation of Greater Mumbai (MCGM):

- 34 out of 60 drugs prescribed at gynaecology out-patient clinic were not available on MCGM schedule
- Of the 264 drugs listed in the Essential Drug List, 140 (53%) were not available on MCGM schedule

If All Patients in PHCs Were To Be Treated Adequately... !

- The Satara district study — if all the patients coming to the PHCs were to be treated adequately, rationally, drug supply to the PHCs would have to be almost doubled, from about 10% to 20% of annual recurring PHC expenses.
- Currently, the annual drug supply to PHCs – Rs. 60,000. i.e. Rs. 2 per capita per year when total drug consumption is Rs. 300 per capita !
- Doubling of the drug supply for 1682 PHCs in Maharashtra would additionally require only Rs. 10 crores; (the annual health expenditure of Maharashtra govt. is around Rs.2,000 crores)
- Compare this with huge wastages by the Maharashtra govt. Expert Committees had opined — Mumbai-Pune Express High Way would be financially unviable. Yet it was constructed by spending 1500 crores and now is being given a running subsidy of Rs 130 crore per year!

Our Demands About Availability of Essential Drugs

- A standard List of Essential Medicines that must be available at subcentre, PHC, RH, District Hospital, must be prepared and revised every three years.

- All Essential Medicines as per this Standard List should be made available regularly and in sufficient amount.
- If patients are compelled to purchase medicines from outside because of non-availability of any of these medicines in the concerned health centres, then Government should reimburse this expense by the patient in the respective health centre.
- Anti-Infective Medicines Routinely Required for HIV Positive Persons be made available, including:
    - ➔ Antimicrobials to treat opportunistic infections — Anti-TB drugs (Isonex, Rifampicin, Ethambutol, Pyrazine amide, Streptomycin, PAS), Co-trimoxazole, Fluconazole, ,acyclovir, sulfadiazine, sulfa-pyremethamine
    - ➔ Wide availability of paediatric formulations;
    - ➔ Anti-Retroviral Medicines – Should be made available through the National AIDS Control Programme
- Monitoring of supply of Essential medicines should be part of the Community Monitoring

KOLKATA DECLARATION
Adopted in the
National Seminar on Pharmaceutical Policy and Access to Essential Medicines
Kolkata on 16-17 April, 2005

The National Seminar on Pharmaceutical Policy and Access to Essential Medicines organised by Jan Swasthya Abhiyan, Federation of Medical and Sales Representatives' Associations of India, National Campaign Committee for Drug Policy and All India Drug Action Network and supported by the World Health Organisation, India country office discussed different aspects of the country's pharmaceutical policy. The seminar was attended by one hundred and twenty eight activists, academics and experts from all parts of the country that deliberated on different issues related to the pharmaceutical sector in India.

The Seminar noted that the country's record in controlling diseases that affect large sections of the people has been far less than satisfactory. The country faces new challenges in the form of increased incidence of "lifestyle" diseases and infections such as HIV-AIDS. This ominous situation admitted in the National Health Policy-2002 needs to be addressed seriously. Disease pattern and common ailments highlighted in NFHS-2 survey should also be taken in consideration.

The seminar also noted the new situation created by the policy of globalisation, privatisation, liberalization and the new product patent regime which together have threatened the national self reliance as well as availability and affordability of essential medicines. The seminar also felt concerned about the worsening situation on the drug price front with its disastrous impact on the poor.

Given the above the Seminar resolves the following suggestions be considered while making the National Pharmaceutical Policy.

Formulation of National Pharmaceutical Policy:

The seminar expressed the need to formulate a National Pharmaceutical Policy that addresses the critical issue of universal access to essential medicines and of national self-reliance. This policy should be prepared by an intersectoral committee of the Ministry of Health & Family Welfare and Ministry of Chemicals & Fertilizers after discussions with all sections that have a stake in the pharmaceutical sector. The two should jointly constitute a National Drugs and Therapeutic Authority, which should be a statutory body with powers to regulate all aspects of the National Pharmaceutical Policy. Apart from experts, this body should also include representatives from health movements.

National Essential Medicines List

1. The Govt., based on epidemiological data, should update the National Essential Medicines List (NEML) and also prepare a Graded Essential Medicines List that is appropriate for each level of the health care system. The National List needs to be adopted by different states and adapted by them based on local conditions and disease profile.

2. The Govt. should monitor and ensure the availability of Medicines listed in the EML. Production of these medicines from the basic stages should be ensured through production control mechanisms.

3. It should be made mandatory that the procurement and use of medicines in Govt. hospitals and public sector undertakings be done based on the NEML .Such procurement should be through transparent procedures. Regular training and incentives to promote use of medicines in the NEML should be provided.

Irrational and Hazardous Drugs

1. Given the proliferation of irrational and hazardous medicines in the market, a special committee of the DTBA should be set-up to weed out all such medicines including irrational Fixed Dose Combinations (FDC) within a stipulated period. Hence forth medicines and fixed dose combinations which are not mentioned in standard text books and other such authentic sources of pharmacological information should be banned and should not be allowed to be marketed. All existing medicines should be re-evaluated at regular intervals on the basis of expert opinion on their rationality, efficacy and need.

2. Injectable contraceptives, transdermal implants and anti fertility vaccines should not be used in the National Family Planning Programme.

3. Adverse Drug Reaction (ADR) Monitoring Centres should be set up in all states of the country and be provided with sufficient resources.

4. When a substantial number of ADRs are reported either in India or abroad for a drug, the same should be referred to the DTAB for withdrawal.

Generic Drug Use

In order to encourage use of medicines in generic names, all medicines sold under generic names should be exempt of duties and taxes. All packages of medicines should carry the generic name more prominently than the brand name.

Medical Education

The curriculum for medical education should include the concepts of essential drugs and rational prescription practices.

Indian Patents Act

1. The Govt. should keep advocating for keeping TRIPS out of WTO provisions and advocate for reopening the issue of exempting the developing countries from Product Patent.

2. The Govt. should ensure that all the flexibilities in the Act are used to promote health and development of the indigenous drug industry.

3. The Govt. should closely monitor the application of Patentability criteria for granting of Patents to ensure that trivial Patents are not allowed and ever greening of existing Patents does not take place.

4. The Govt. should liberally interpret the Doha Declaration of 2001 by declaring situations of emergency/urgency in the case of diseases that are present in epidemic or endemic forms or where their prevalence constitutes a health emergency. In such situations Compulsory licenses should be issued without delay.

5. Govt. should also facilitate the issue of compulsory licenses to remedy situations of non availability or high price of a patented drug or where an export market exists and is not being addressed.

Drug Production and Availability

1. To ensure production from the basic stage, ratio parameters between manufacture of formulation and bulk drugs should be reintroduced.

2. Production Control mechanisms should be introduced to ensure that all manufacturers produce a certain proportion of drugs from NEML that are Essential.

3. The new policy of allowing 100% equity participation of MNCs in the pharmaceutical sector needs to be changed and majority equity participation by the multinational companies should only be permitted if new technology is brought in by them for manufacturing and research.

4. Restrictions in the form of tariffs and other non-tariff measures should be imposed on the import of bulk drugs or formulation for which adequate production capacities exist in the country.

5. Prevailing systems of loan license or third party license should be abolished. Mention of the name and address of the manufacturer should be clearly indicated on the label of each medicine, and the license holder should be held responsible for all complaints, compensation and replacement of medicines.

Drug Pricing

1. All drugs should be brought under price control given the fact drug expenditure in India is more than half the health care expense and also because more than 80% of health care expenditure is met by patients themselves. Mechanisms that are transparent and easy to administer should be put in place to control prices and the system of price control should benefit the efficient producer. In no case should the mark up allowed be more than 100%.

2. Trade margin, those to including wholesalers and retailers should not go beyond 30%.

3. National Medicines Pricing Authority should be established as a quasi judicial body which should be given sufficient legal power to punish manufacturer for violation of ceiling prices.

4. For imported medicines, provision of cost data and manufacturers price certificate should be made mandatory.

5. All cancer and HIV/AIDS medicines and orphan medicines should be exempt from all taxes and duties, including import duties.

Public Sector

The production of drugs for the poor and the neglected diseases can only be ensured by making public sector companies major producers in these areas. Public sector medicine companies such as IDPL and HAL should be revived and they should be provided with the support in the form of sectoral reservation, preferential treatment in the cases of Govt. purchases, etc. These companies would need to be provided a leading role in drug manufacture in the case of compulsory licenses issued in situations of national emergency and extreme urgency. New public sector companies should be promoted for producing those essential medicines that are not being produced by private companies at an affordable cost.

Research and Development

1. A major national effort should be made to increase original drug research based on the strength of our national research institutes, laboratories and the Universities and also on the biodiversity and the medicinal plant wealth of our country. The research institutions should be provided with adequate funds for drug research .Regional drug research centres may be established in states where infrastructural facilities are already available. Universities should be encouraged to offer courses so as to produce adequate and high quality human resource pool for modern drug research related activities. The Public Sector should be promoted to play the leading role in R&D activities.

2. Public funded Research Laboratories should co-ordinate their activities. The research activities of publicly funded research organisations should not duplicate empirical drug discovery projects

in the pharma R&D model, but should concentrate on generating the knowledge base for the identification and exploitation of new intervention points for medicines.

3. All medicines developed in the country should be exempt from taxes and duties for 10 years.

4. A comprehensive legislation on the ethical conduct of clinical trials should be enacted in line with the Helsinki Declaration and other international covenants, treaties and declarations so as to provide for strict guidelines for obtaining informed consent, for protection of the health of subjects of such trials.

5. Outsourcing of clinical trials for MNCs should be closely monitored by a specially constituted Standing Ethics Committee set up in each state.

6. All information about protocols and the results of the clinical trials approved by the DGCI should be in the public domain.

7. Phase IV of the clinical trials should be mandatory and should not be replaced by the PMS studies by he pharmaceutical companies.

Quality Control and Drug Information

1. The manufacturer should be fully responsible for the quality of a medicine. A separate Food and Drug Court should be made responsible for redressal of complaints and for trial of those responsible for manufacture and sale of spurious and sub-standard drugs.

2. The Drugs and Cosmetics Act should be suitably amended to provide for exemplary punishment to those found guilty.

3. The drugs control organisation both at state and central levels

should be adequately strengthened in terms of infrastructural facilities and human resources.

4. Each state should have at least one well equipped drug testing laboratory under the control of the state drug controller.

5. The state and central drugs controllers should have their own websites. Among other information these websites should publish updated information on banned and withdrawn drugs including their brand names as well the current laws in operation.

6. A consensus should be developed after discussion with manufacturers of all sectors for developing minimum benchmark of good manufacturing practice which then can be embodied in the Schedule 'M' of the Drugs & Cosmetics Act.

7. Consumers should be allowed to get tested medicines of doubtful quality at any Govt. approved test laboratory.

8. New colleges of pharmacy should be opened to eventually ensure that all retail pharmaceutical outlets have the services of a trained pharmacist.

9. The outdated Magic Remedies Act should be replaced by a new Act.

10. To disseminate unbiased information of medicines, Govt. should develop an independent process for information. The National Formulary should be updated and published regularly. Standard treatment protocols and guidelines for common ailments and for every tier of the health system should be prepared and disseminated. Doctors, pharmacists and staff nurses should be trained in treatment protocols and guideline. All hospitals and medical centres should be encouraged to prepare and use their own formularies.

Drug Promotion

1. A National Ethics Committee on Promotion of Medicines (NECPM) in which there is adequate representative of civil society organisations should be formed to monitor all promotional efforts
2. A code of ethics for marketing of medicines should be adopted by NECPM and made obligatory for all the manufacturers.

3. All promotional materials for health professionals should be screened and approved by NECPM and all advertisements in the regional press be scrutinized and approved by a state level Ethical Promotion Committee.

4. Gifts except minor items, inducements, sponsoring of meetings and entertainment of the members of the medical profession and those who are related to drug prescription, purchase etc by drug companies should be banned so that these do not influence prescribing practices.

5. Drug companies should contribute funds to the drug control authority for the conduct of Continuing Medical Education programme for doctors

6. A cap on drug promotional expenditure drug companies should be fixed and enforced.