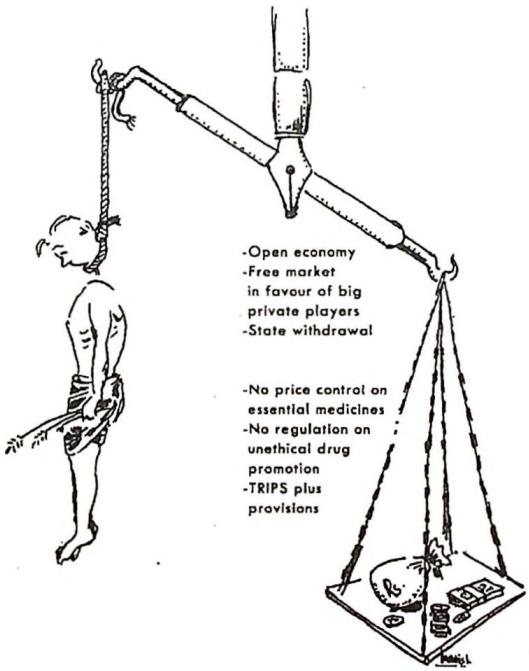
Medicine Prices and Affordability

- A Policy Brief on Drug Pricing



disease..... drugs..... debt.

March 2009

All India Drug Action Network (AIDAN)

A Campaign Group for Rational Drug Therapy and Policy!

http://www.aidanindia.wordpress.com

Medicine Prices and Affordability, March 2009

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"This pricing brief document is dedicated to the memory of Dr. Wishvas V Rane (1930-2008) one of the founders of AIDAN and beloved senior most drug activist".

Drug Prices and Affordability

Abstract: This policy brief discusses the issue of medicine pricing and affordability for the common people of India. This document gives specific examples of overpricing. A decaying public health system and a market riddled by overpriced, irrational and unscientific medicines aggravates the lack of access and affordability. Several Government of India committee reports have suggested some form of medicine price regulation. As this brief points out, even in the so-called advanced countries of the West, some form of governmental regulation is prevalent. Health is too precious to be left to market forces – a thinking which even a 'free market' economy like the US and its new president elect is veering towards – the meltdown has made it clear that access to affordable health is a basic human right.

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Drug Pricing Policy Brief

DRUG PRICES AND AFFORDABILITY

India has a booming drug industry and has contributed to making generics at low prices worldwide. We are rightly proud of this. But medicines within India are overpriced and unaffordable, a glaring silent violation of human rights, that gives sleepless nights to many patients leading eventually to their misery and penury.

The margins in medicines are extremely high often reaching 1000-4000 percent. More "players" have not resulted in lower prices of medicines or for that matter lower cost of health services. Demand is supplier induced. The health market creates and promotes wants.

How costly are drugs? How many days income would a worker have to spend to pay for the cost of treatment of a particular condition?

Sl. No.	The condition or drug or the intervention	Cost and duration of treatment of the same	Number of days person will need to work as a labourer at the rate of Rs.60/ per day
1.	Multi-drug resistant TB	Rs.97,389 for person under 45 kg and Rs.143,748 for a person above 45 kg for 27 months	Four and half to six and half years
2.	Iron deficiency anemia (using Dexorange)	Rs.3,744 for 6 months	62 days of daily wage.
3.	Diabetes using oral glimepiride 2 mg	Rs.3660 per year	61 days of daily wage
4.	Prevention of Hepatitis A	Rs.1800	30 days of daily wage

Where as an unskilled worker in USA or UK needs to work for 10 minutes to buy 10 tablets of Paracetamol but in India a daily wage worker will have to work at least one hour. And our Paracetamol is one of the cheapest in the world!

Not only a large number of people cannot afford medicines but often have to pay comparatively significant amounts of their wages or money taken on loan for purchase medicines that they can ill afford. Also the majorities of medicines used are not accessible through public health outlets and so have to be out of pocket expense.

The impact of the jobless economic growth model which has further been worsened by the economic recession, loss of livelihoods and decreasing purchasing power of the marginalized has had significant public health damaging impact especially on women & children. The spiraling cost of basic needs specially food, besides shelter, transport etc has left much less for even essential health needs like medical care & medicines.

Costing Less than a Cup of Tea?

To say some drugs cost less than a cup of tea, and therefore should not be price regulated, is a travesty. In many cases medicines are to be taken several times a day and for many conditions at a time. No doctor prescribes a single medicine. Again some medicines are taken for months and years together. Many cups of tea in urban areas are Rs 2 and more per cup! As we show above forget tea, not even a square meal a day is affordable.

Cost of Treatment with Biotechnology-based Drugs[1]

- Abciximab (antianginal, Eli Lily): Rs. 39,480 for a 60 kg man per day
- Epoeitin alfa (Wepox/*Wockhardt*. Treatment of anemia of chronic renal failure): Rs. 10,200 for 8 weeks for a 60 kg man AND
- Rs. 1912 to 11475 *per week* for a 60 kg man thereafter
- Interferon alpha-2a (Roferan-A/Nicholas Piramal)used in types of leukemia: Initial therapy costs of Rs. 43,552- Rs 1,30,656 then maintenance therapy costs of Rs. 1,06,158- Rs.3,18,474 (6-18 months tt cost)
- Etanercept (Enbrel/Wyeth) –in severe arthiritis: Rs. 18,131 per week of therapy which has to be taken long term.

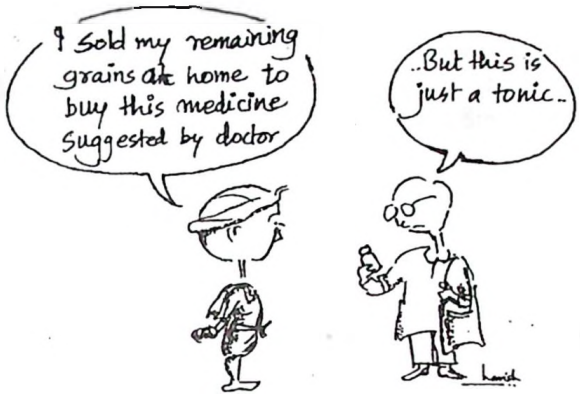
Price of Glivec, an anti-cancer drug

- Novartis: Rs 1,30,000 per month
- Price of Indian generic equivalents: Rs 10,000 per month

Still unaffordable

The Problem of Poverty amidst Plenty

- Medicines are overpriced and unaffordable in India..
- Medicines constitute 50 to 80 percent of health care costs in India.
- Health care is the second-most leading cause of rural indebtedness, after dowry.
- There is no universal health insurance in India; even if there were, regulation of prices would result in considerable savings.
- Because of a crumbling public health system, the first choice of patients is a private practitioner which means more out of pocket expenditures apart for loss of wages etc.



What is the extent of overpricing? We give below a comparison of prices of LOCOST Baroda, a small scale Schedule M certified manufacturer and the market.

Name of Drug	Use	LOCOST selling prices per tab (Rs)	Market selling prices per tab (Rs)
Albendazole 400 mg	For worms	Rs. 1.10	Rs. 9 to 12
Amlodipine 5 mg	In high blood pressure and as antianginal	Rs. 0.25	Rs. 1.40 to 5.00
Atenolol 50 mg	In high blood pressure and as antianginal	Rs. 0.20	Rs. 4 to 22
Enalapril 5 mg	In high blood pressure mild to modrate	Rs. 0.30	Rs. 1.60 to Rs. 2.30
Fluconazole 150 mg	Anitallergic	Rs. 0.20	Rs.0.50 to Rs. 3.00

Source of Prices : Circa 2008 from MIMS / CIMS et al

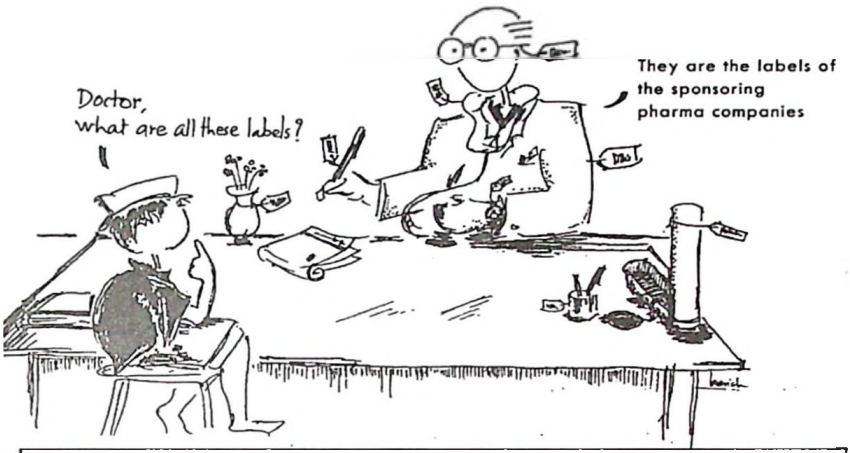
Market Failure and the Pharma Market in India

In markets where competition works, the most bought is the cheapest brand. Many producers bring down prices. Sellers and buyers are equally well-informed about the product before making a purchase.

"India is a good market for us. We can price the medicines any which way we want. Even the Government is moving out of regulating medicine prices. Nothing can stop us now....."

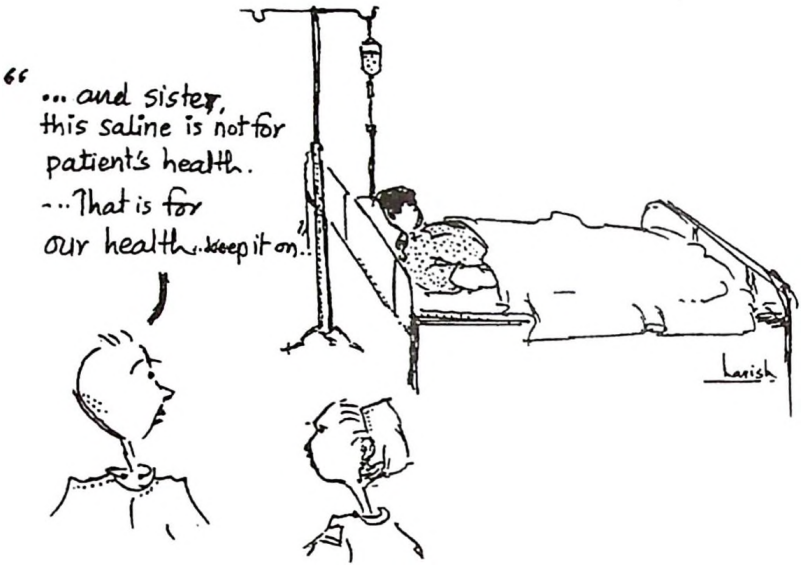
Let us review some facts about the pharma industry in India.

- Competition does not work in India's pharma formulations market.[2] The notion of a free market in pharma and health services is a contradiction in terms (see also Table 1 below).
- However India's pharma sector is a "free" market in a different sense for a long time: one could make all kinds of irrational medicines from fresh human placenta, animal liver and cattle blood as also arbitrary combinations of different kinds of medicines and sell them at arbitrarily high prices.
- In India, the same drug is sold at vastly different prices by equally reputed companies and often by the same company.[3]
- Brand leader is often the price and volume leader! That is the most popular brand of a drug is also often the highest priced. (In terms of cars, this means a majority buys Mercedes and not Maruti 800.)



Medicines are the only commodity in which the end-user (the paying patient) does not decide what to buy and at what cost. The doctor prescribes and the patient pays. In addition, in India every doctor decides on his/her own which brand of which medicine to prescribe.

- There is no choice for the consumer in the medicines market. Unlike in case of other commodities the purchaser of medicines is extremely vulnerable at the time of making a decision to purchase a medicine - he/she is seeking immediate relief from suffering.
- These asymmetries in information - that is unequal information that does not help the patient in making an informed, considered choice - in the doctor-drug company interface as much as in the doctor-patient and drug company-patient, is what leads to market failure. This special nature of the pharma sector is the reason why even in market economies, all issues related to medicines including their prices are the subject of regulation by their Governments. The only exception is the USA – even in the USA the prices of medicines are indirectly regulated by health maintenance organisations negotiating prices to be paid on prescription costs. (The Government's own committees have reported that even in the so-called free market countries there is price control of some kind or the other.)



- Pharma is the only sector in India (and probably in the world) where government tender procurement prices are 1-3% of the retail market prices! This if anything indicates the level of overpricing.[4] An example: for the Tamil Nadu Government, a drug company bids to supply Albendazole 400 mg tablets, a medicine for worms, at a mere 35 paise per tablet, while brands of this drug sell for Rs.12/- in the market.

- India's pharma markets are full of unnecessary, unscientific and therapeutically useless drugs. This leads to further market distortion and market failure -apart from adding to the cost of prescriptions and complications in health recovery. We need to immediately weed out all these medicines by allowing only medicines as per the WHO essential drug list (March 2007).

- If one studies the ORG-Nielsen list of top-selling 300 medicines accounting for more than Rs 35,000 crores sales (almost 90 percent of the retail market), atleast 60 percent of the top-selling 300 medicines are not in the National List of Essential Medicines (NLEM). Therefore 2/3rds of medicines sold in India are not essential medicines by the Government's own definition.

Table 1: A Glimpse of the 'Free' Market of Branded Medicines - What happens when there is no price regulation?

Sl. No.	Name of Drugs	Drug under price contro	Lowest Price of Brancd Brand in Rupees/Brand Name / Manufacturer	Highest Price of Brand in Rupees/ Brand Name Manufacturer	Highest priced brand / lowest priced brandx100
Medicines for bacterial infections : like pneumonia, urinary tract infections					
1.	Ofloxacin 200 mg	No	Rs. 3.20/Zo/FDC	Rs.31.00/ Tarvid/Aventis	969%
2.	Levofloxacin 500 mg	No	Rs. 6.82/Levoflox/Cipla	Rs.95.0/Tavanic/	1392%
3.	Ciprofloxacin 500 mg	Yes	Rs.3.90/ Zoxan/FDC	Rs.8.90/ Cifran/Ranbaxy	228%
4.	Azithromycin 250 mg	No	Rs.8.50/Zathrin, FDC	Rs.39.14/Vicon/ Pfizer	460%
Medicines used in Viral Infections including HIV / AIDS					
5.	Zidovudine 100 mg	No	Rs.7.70/Zidovir/Cipla	Rs.20.40/Retrovir/ GSK	265%
Medicines used in Heart Disease, Hypertension, High Cholesterol					
6.	Amlodipine 5 mg	No	Rs.1.51/Amlodac/ Zydus Cadila	Rs.6.00/Amlogard Pfizer	397%
7.	Atenolol 50 mg	No	Rs.0.40/Ziblok/FDC	Rs.2.45/Tenormin/ Nicholas Piramal	612%
8.	Valsartan 80 mg	No	Rs.5.90/Valzaar / Torrent	Rs.41.00/Diovan/ Novartis	694%
Medicines used in Diabetes					
9.	Pioglitazone 15mg	No	Rs.0.99/Pio/Systopic	Rs.6.00/Piozone/ Nicholas Piramal	606%
10.	Glimepride 1Mg	No	Rs.0.80/Glimestar/ Discovery / Mankind	Rs.5.30/Amaryl/ Aventis	696%
Medicines used in Cancer					
11.	Tamaxifen 10 mg	No	Rs.2.70/Tamodex/ Biochem	Rs.20.00/ nolvadex/ ICI	741%
12.	Letrozole 2.5 mg	No	Rs.9.90/Oncolet/	Rs.181.50/	1833%

Sl. No.	Name of Drugs	Drug under price control	Lowest Price of Brancd Brand in Rupees/Brand Name / Manufacturer	Highest Price of Brand in Rupees/ Brand Name Manufacturer	Highest priced brand / lowest priced brandx100
Medicines for Psychiatric Ailments					
13.	Risperidone 2 mg	No	Rs.1.69/Respidon/ Torrent	Rs.27.00/Risperdal Ethnor	1598%
Medicines for Metabolic Disorders					
14.	Risedronate 35mg	No	Rs.50.12/Risofos/Cipla	Rs.500.00/Actonel/ Aventis	997%
Medicines for Arthritis					
15.	Leflunomide 10mg	No	Rs.8.00/Rumalet/Zydus Cadila	Rs.44.00/Arava/ Aventis	550%
Medicines for Erectile Dysfunction					
16.	Sildenafil citrate 100 mg	No	Rs.29.16/Penegra/Zydus Alidac	Rs.584.00/ Viagra/Pfizer	2002%

Drug Pricing Policy over the Years

Administrative pricing systems for medicines were initiated in 1962, in the wake of the Chinese aggression and the declaration of emergency in 1962. The Defence of India Act was invoked to curb the spiraling prices of medicines. The Drugs (Display of Prices) Order 1962 and the Drugs (Control of Prices) Order 1963 were promulgated. These orders had the effect of freezing prices of medicines as of 1st April 1963. Further attempts to regulate prices were made through the Drugs Prices (Display & Control) Order 1966; the Drugs (Prices Control) Order 1970 promulgated under the Essential Commodities Act 1955 (ECA); the Drug (Prices Control) Order 1979 based on the Drug Policy 1978 – the latter policy was an outcome of the landmark Hathi Committee Report of 1975. The thrust of its 224 recommendations was to re-emphasize the leading role for the public sector, the setting up of a National Drug Authority, preference to Indian Sector over the foreign sector, indigenous production of raw materials, selective price control on prices of medicines etc. However it is probably the Patent Act 1970 that has had the greatest effect on lowering drug prices and making India's Pharma industry largely a force to reckon with.

Price controls, after DPCO 1979, have been systematically reduced over the years (see Table2 "Comparative Chart Summarizing Price Control Scheme under Various Drug Price Control Orders"). Industry did not, and does not, like controls and indeed a major part of the problem was the way price controls were administered. Also since the nineties, there has been a significant paradigm change among policy makers in their view of business and industry. Economic reforms have meant the welcome removal of the licence-quota-permit Raj. There was hope that the attendant corruption would go.[5] With liberalisation, there has been a gradual dilution of the role of the Government even in sectors like health and education, with the naïve hope that the market would take care of the situation.[6] Price control has remained, albeit in a diluted form, and it was the stated aim of the Pharmaceutical Policy of 2002 (henceforth PP 2002) to reduce the "rigors of price control". It was widely expected by industry that about 30 to 34 medicines alone would remain under price control.[7]

Table 2: Comparative Chart Summarizing Price Control Scheme under Various Drug Price Control Orders

	DPCO 1979	DPCO 1987	DPCO 1995	Present March 2008
1. No. of medicines under Price Control control	347	142	76	74
2. No. of categoriesunder which the above medicines were categorized	3	2	1	1
3. MAPE % allowed on normative/National exfactory costs to meet post-manufacturing expenses and provide for margin to the mfrs.				
Category I	40%	75%	100%	100%
Category II	55%	100%	N.A.	
Category III (Single ingredient Leader products)	100%	N.A.	N.A.	
4. Total Domestic pharma sales covered under Price-control (Approx)				

N.A. = Not Applicable

Drug Price Control in Other Countries

Even the so-called free market countries of the EU and UK have some form of controls – price controls, volume controls and cost-effectiveness controls. Twelve out of 16 West European countries control prices of medicines directly. On the contrary, it appears, Indian policy makers are intent on throwing out the baby with the drug price control basket.

In fact, price regulation of medicines is the norm all over the world, except the USA, which unfortunately India is trying to emulate. Even in USA, drug companies and health insurance companies always negotiate prices. But the system excludes large numbers of the poor and especially makes medicines costly for the elderly.[8] One in three non-elderly Americans — 74.7 million — was without health coverage for all or part of 2001-2002[9].

UK has its Pharmaceutical Price Regulation Scheme.[10] All European Union (EU) countries have a form of price regulation. In setting prices, these countries use therapeutic comparators and the price of products in other EU markets. Denmark, Greece, Finland, Ireland, Italy, the Netherlands, Portugal, and Sweden set a maximum price in relation to prices in neighboring countries. Belgium, France, and Italy set prices in relation to relative cost, prices elsewhere in the EU, and the contribution made to the national economy. In Austria, France, and Spain there are volume-cost and other rebate schemes. Spain and the United Kingdom set their prices to ensure a rate of return within a particular profit range.[11] Information can be obtained from the following websites about medicine pricing policies in different countries.

Medicine Policy in Netherlands

Canada has a Patented Medicines Prices Review Board, France has a Transparency Commission and Economic Committee on Medicines, Egypt has all medicines under price control, Italy has restricted wholesale margins, Germany has its reference pricing system. Some system of price monitoring and price regulation prevails in Japan, Netherlands, China, Indonesia, Colombia, etc. In some of these countries, drug pricing is tied with national health system reimbursements and or insurance schemes. In response to these measures, big pharma lobbies like Pharma scream "Foreign price and

access controls on pharmaceuticals distort and inhibit International Trade" and want the US Government to "take action", meaning twist arms in other ways.[12] *Indeed, it is worth pondering, how come all the developed free market economies do not have a free market with respect to pricing of medicines?* And the drug companies there fund their R & D from sales!

In the absence of universal free access to health insurance and/or meaningful price controls, in India, the havoc on the majority of the population can well be imagined.

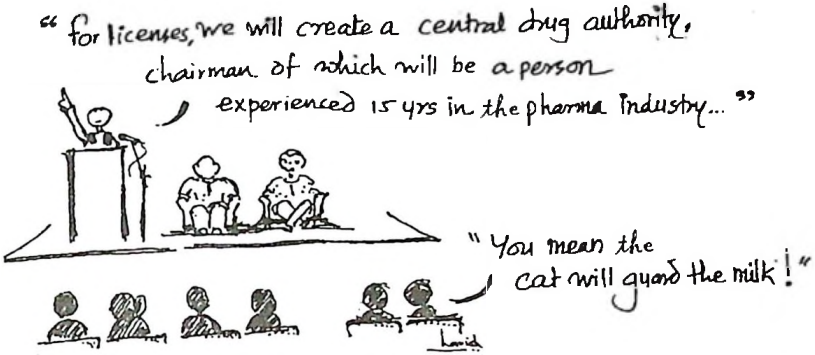
Total decontrol, or even a semblance of it, as desired by free marketers, is going to the other extreme and has had, and will have, deleterious effects on not only the poor, but on even the middle class of India.

Anomalies in Pricing Policies

In fact, the *Report of Drug Price Control Review Committee* of the Government of India had noted:[13]

> ...in most other countries, the regulation of the drug prices is considered necessary to contain public expenditure due to government's role in funding social health and insurance schemes that cover hospital and out-patient drugs. The price regulations are used as an instrument to keep their health budgets within reasonable limits. In these countries, a substantial proportion of the population is covered through health insurance and public health schemes. As a result, the consumers are not affected directly by the high prices of medicines or high costs of medical services, but are made to pay for the increased prices/cost through high insurance premium. As opposed to this, a substantial proportion of the population in India is market dependent and have to meet all their expenses out of their own pocket on this account, making price regulation of pharmaceutical products in the market unavoidable.

Nevertheless in actual behaviour the Government has chosen to ignore the above advice (and many such more recent advice) as evidenced most recently by its intentions to "lessen the rigors of price control"



in Pharmaceutical Policy 2002.[14] The 2002 Policy itself is riddled with illogic as pointed out in a Supreme Court Petition by AIDAN and others.[15] Briefly, PP 2002 and all previous policies (except possibly the first one in 1978) have some common problems: the turnover-based, market share criteria chosen to keep medicines in and out of price control tend to be faulty and lead to anomalies:

- Most essential and useful medicines are kept out of price control.
- Non-essential and harmful medicines like analgin, phenylbutazone, Vitamin E, sulphadimidine, mebhydrolin, diosmine panthonate and panthenols, bacampicilin, etc is under price control.
- Medicines for HIV/AIDS, cancer, hypertension, coronary artery disease, multidrug resistant tuberculosis, diabetes, iron deficiency anemia, ORS, tetanus, filariasis, vaccines (new) for rabies, hepatitis B, sera for use in tetanus, diphtheria, Rh isoimmunisation, anticonvulsants and antiepileptics, diptheria, snake bite, suspected rabid dog bite/rabies, etc. fall outside price control (See boxes below).
- Price control, since it is based on market share criteria, produces only partial regulation. Chloroquine for malaria would be under price control but not equally important other anti-malarials.[16] True also leprosy medicines and analgesics.

- Of the 300 top selling brands in the ORG Nielsen list of October 2003, only 36 (that is only 12 percent) were price controlled
- The rest, that is 88 percent, were not.[17]

There is also a tremendous divergence in the goals of the Pharmaceutical Policy 2002 and the National Health Policy 2002.[18] The former seems to address the needs of the drug industry lobby while the latter is more focused on the real health problems of the country. A tragic dichotomy with the people suffering as a result, a case of the left hand (Chemicals and Fertilizer Ministry) of the Government not concerned with the right hand (Ministry of Health and Family Welfare)[19].

The Report of the Standing Committee on Chemicals & Fertilizers, 2005-06, Fourteenth Lok Sabha observes:*

> The Committee's examination revealed that though, there is a provision that a strict watch will be kept on the movement of the prices and the Government may determine the ceiling levels beyond which increase in prices would not be permissible, this provision has seldom been applied. In this context, some of the State Governments have also informed that when the cases of high prices of Anti-cancer drugs, Antibiotics, Nutraceuticals and Cetrizine were referred to the National Pharmaceutical Pricing Authority (NPPA), the latter conveyed its helplessness in curtailing the high prices. The Committee are unhappy over this unsatisfactory state of affairs and desire that the situation should be remedied forthwith. They therefore, recommend that for the category of medicines for the same therapeutic use, the Government should determine a reasonable ceiling beyond which increase in prices may not be allowed.

*Recommendations/Observations of the Committee, Para 10, in *Availability and Price Management of Drugs and Pharmaceuticals*. Seventh Report, Standing Committee on Chemicals & Fertilizers, 2005-06, Fourteenth Lok Sabha, Lok Sabha Secretariat, New Delhi, September 2005

Recommendations of Other Expert Committees

Several other expert committees set up by the Government of India, in post-liberalization times, have also stressed the importance of drug price regulation. For instance: the Drug Price Control Review Committee of 1999, the Sandhu Committee of 2004, and a Task Force appointed by the PMO in 2005 and chaired by Dr. Pronab Sen from the Planning Commission, the Commission on Macroeconomics and Health 2004, etc. However industry does not want controls of any kind and in accordance with the wishes of the pharma industry, the number of medicines in the price control basket has come down over the years from over 347 in 1979 to 74 in 1995 – it would have been less than 30 if the Pharmaceutical Policy 2002 were not stayed by the Supreme Court. The Court directed the Government of India to first decide the basket of essential medicines to be put under price regulation and a methodology thereof.

Task Force Report Recommends Ceiling Prices on Formulations

The Government of India appointed a Task Force chaired by Pronab Sen, Principal Adviser at the Planning Commission, "to Explore Options other than Price Control for Achieving the Objective of Making Available Life-saving Drugs at Reasonable Prices". The Task Force submitted its report in September 2005 and if *implemented* they should alleviate many of the gross distortions in drug pricing.[20]

The Task Force recommended that the National List of Essential Medicines (NLEM) 2003 should form the basis of drugs for price control/monitoring[21]:

To support the process the Government should announce the ceiling price of all drugs contained in the NLEM on the basis of the weighted average price of the top three brands by value of single ingredient formulations prevailing in the market as on 1.4.2005. In cases where there are less than three brands, the average of all existing brands would be taken. The ORG-IMS data can be used for this purpose

initially with a retail margin of 20%. For drugs, which are not reflected in ORG-IMS data, the NPPA should prepare the necessary information based on market data collection. In the case of formulations, which involve a combination of more than one drug in the NLEM, the ceiling price would be the weighted average of the applicable ceiling prices of its constituents. Excise duty should continue to be payable on the actual MRP of the individual medicines. In the case of drugs not contained in the NLEM, intensive monitoring should be carried out, for any new formulations based on existing APIs (Active Pharmaceutical Ingredients), manufacturer concerned would be required to submit its intended price along with application for marketing approval to the regulator, which would be granted only if the indicated price is consistent with relevant ceiling price. The NLEM should be revised every three years.

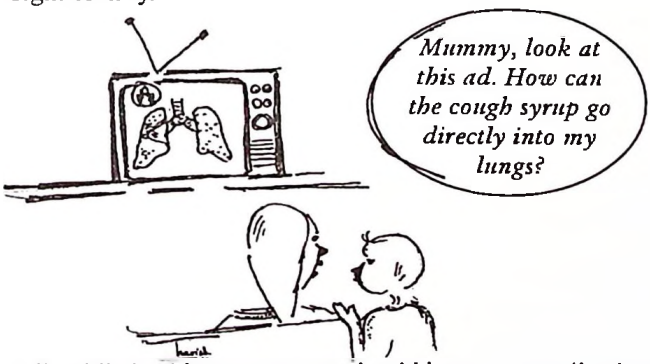
Price Regulation .... against TRIPS?

- TRIPS is silent on Price Control
- Doha Declaration and Art 7 (Objectives) and Art 8 (Principles) of TRIPS assert members right to protect public health over and above TRIPS/WTO.
- "Each member has the right to grant CL and freedom to determine grounds upon which such licenses are granted." (Doha Declaration)
- Trade cannot be given primacy in comparison to health and human rights.
- One of the grounds for issue of Compulsory Licenses according to the Patents Act of India is when the patented medicine is "not available to the public at reasonably affordable price."

Recommendations

Post-liberalisation, the State clearly has a welfarist and interventionist role, especially in the areas of health, education and removal of hunger. The legitimacy of the State as an instrument of ensuring the right to health care and distributional justice needs to be asserted.

- Price regulation of medicines is a key public policy measure for health of India's teeming masses. Only the Government of India can do it. Like it has done for cell phone rates, insurance premia, electricity tariff, bank interest rates, etc.
- All market distorting factors like irrational fixed dose combinations, hazardous and bannable medicines should be removed.
- Unfair and unethical practices of drug companies like drug promotion, which often includes fancy gifts, and trips abroad all need to be curbed. These will reduce health expenditures significantly.



- All public health programmes should have a centralized pooled procurement system like Tamil Nadu and Delhi State governments.
- There should be a strict watch on prices of lab investigations, medical procedures and surgical operations too. Why is it cataract surgery with Intra Ocular Lens Implant can be done at Rs 600 in the world class Arvind Eye Hospital in Madurai whereas most other "reputed" private hospitals charge Rs 20,000 and above? In fact the Government happily reimburses the latter for its employees.

Also let us add that all these are not against TRIPS in anyway.

Demands of AIDAN on Making Medicines Affordable

1. Regular revision of the National List of Essential Medicines every 2-3 years, as well as revision of the list of drugs under price control.
2. Price regulation of all essential medicines in the National List of Essential Medicines based on therapeutic class than on individual drugs. Inclusion of all vaccines and recombinant DNA technology based products in the list.
3. Full utilisation of the safeguards and flexibilities under TRIPS.
4. Ensuring improved availability, accessibility and affordability of drugs including vaccines and sera in the public health system; through quality conscious pooled procurement systems and promotion of manufacture of essential medicines such as expensive antibiotics, drugs for malaria, TB including MDR-TB, HIV/AIDS, and non communicable diseases.
5. Limiting new drug approvals only to those with a distinct therapeutic, safety or cost advantage.
6. Creation of a single regulatory agency to look into drug pricing, approval, and quality issues.
7. A regularly updated Indian National Formulary on the lines of British National Formulary to provide unbiased prescribing information and rational guidelines for use of drugs.
8. Regulation of unethical and extravagant drug promotion that leads to high prices as also irrational prescription practices.

Endnotes

1 Thanks to Dr Anurag Bhargava of JSS Bilaspur for these data, Sep 2007.

2 The API or bulk drugs market is a better example of many players reducing prices – however even oligopoly like in the vital anti-TB segment of rifampicin and ethambutol has led to market failure. For more discussion on market failure in the pharma market in India, see Impoverishing the Poor: Pharmaceuticals and Drug Pricing in India, op.cit.

3 The same drug in the same strength manufactured by two trusted companies can vary from 2 times to 20 times in their prices, which has no credible explanation other than overpricing. Levofloxacin used in infections is sold by Cipla is 7 rupees per tablet, while Aventis sells it at Rs. 95 per tablet. What is worse is that costlier medicines most often sell more because of more aggressive promotion. Hence the next statement: brand leader is also the price leader

4 See for instance: Srinivasan, S. "How Many Aspirins to the Rupee? Runaway Drug Prices", Economic and Political Weekly, February 27-March 5, 1999.

5 The corruption has not gone but it is probably less even as functionaries of the State find newer and newer ways of rent collection. Even today getting new drug approvals and licenses entails palm greasing for most. The fact irrational and hazardous medicines continue to exist is probably another source of corruption. It is also in the interest of contract research organizations and many Pharma manufacturers and retailers to keep a lax State lax.

6 But reforms are now getting a more balanced tone. With the State, or at least sections of it, realizing that there is no alternative for the State but to actively shape the content of health services.

7 The pricing part of the policy that would lead to further decontrol has been stayed by the Karnataka High Court; the matter is now in the Supreme Court pending appeal by the Government of India. For a critique of the Pharmaceutical Policy 2002, see Chapter 1 of LOCOST/JSS 2004, "Missing the Woods for the Trees: Drug Price Control and Pharmaceutical Policy 2002".

8 "Prices Of Most Popular Drugs For Seniors Rose Nearly Three-And-One-Half Times The Rate Of Inflation Last Year — Prices Of 27 Of The Top 50 Drugs Sold To Seniors Rose More Than Three Times The Rate Of Inflation" at / www.familiesusa.org/site/PageServer?pagename=Media_Out_of_Bounds, July 9, 2003

9 See <http://www.familiesusa.org/site/DocServer/Going_without_report.pdf?docID=273>

10 See <http://www.doh.gov.uk/pprs/index.htm>

11 Information can be obtained from the following websites about medicine pricing policies in different countries.
Medicine Policy in Netherlands <http://www.netherlands-embassy.org/article.asp?articleref=AR00000251EN>
Pharmaceutical Benefits Pricing Authority (Australia)
<http://www.health.gov.au/pbs/general/pricing/pbparpt.htm>
Patent Medicine review Board sets the medicine prices in Canada.
<http://www.pmprb-cepmb.gc.ca/english/home.asp?x=1>
European Commission website has information about pricing policies of a number of countries including France, Germany, Sweden, United Kingdom. Following is the website.<http://pharmacos.eudra.org/>

The Netherlands Pharmaceutical Pricing and Reimbursement Policies
<http://pharmacos.eudra.org/F3/g10/docs/tse/Netherlands.pdf>

Australia <http://pharmacos.eudra.org/F3/g10/docs/tse/Australia.pdf>

New Zealand Pharmaceutical Pricing and Reimbursement Policies
<http://pharmacos.eudra.org/F3/g10/docs/tse/NewZealand.pdf>

Finland Pharmaceutical Pricing and Reimbursement Policies
<http://pharmacos.eudra.org/F3/g10/docs/tse/Finland.pdf>

Sweden <http://pharmacos.eudra.org/F3/g10/docs/tse/Sweden.pdf>

WHO website on <http://www.who.int/medicines/organization/par/ipc/drugpriceinfo.shtml>

See Annexure 1 for the relevant detailed extracts from the DPCRC Report.

12 "Yet, government-imposed price and market access controls serve as a barrier to trade that diminish or eliminate the very incentives that lead to the continued development of innovative and safe pharmaceutical products, while inhibiting or preventing patient access to the latest pharmaceutical innovations. Moreover, those controls deny American firms and workers the ability to compete on fair and equitable terms in foreign markets and undercut the value of intellectual property rights." For full submission see, PhRMA "Special 301" Submission Appendix C, "U.S. Government Needs To Take Action To Address Foreign Price Controls" at <http://www.phrma.org/international/Appendix_C_Market_Access.pdf>.

13 Report of the Drug Price Control Review Committee, Dept of Chemicals and Petrochemicals, New Delhi, October 1999. Hereafter DPCRC Report, 1999.

14 See even more recently, "Price control to be brought down to 35 drugs in Pharma policy 2005, monitoring on 319 others", Friday, November 25, 2005, at

<www.pharmabiz.com>. As of going to the press, Jan 2006, a draft policy is in circulation for comments available at the NPPA website.

15 AIDAN and ors. Versus Union of India in the Supreme Court of India –WP (Civil) 423/2003). See also for arguments of the case summarized in Impoverishing the Poor: Pharmaceuticals and Drug Pricing in India, LOCOST/JSS, Baroda/ Bilaspur, December 2004. Hereafter LOCOST/JSS 2004.

16 The price control on drugs of any category is partial at best, with only one or two drugs of a category of drugs being represented in the price controlled list. For example, in the case of NSAIDS only ibuprofen, aspirin, and phenylbutazone are represented in the previous DPCO list while in the market under the category of NSAIDS 21 drugs are available. This partial representation of drug categories seriously dilute the efficacy of the DPCO in making essential drugs available to people, especially by shifting demand away from a price-controlled drug to those alternative drugs not under price control.

17 Out of the top 300 top selling brands only 115 brands were of drugs, which are included in the National List of Essential Medicines 2003; i.e. 62% of brands were of drugs, which were not considered relevant by experts to be included in the National List of Essential Medicines (2003). These include more expensive alternatives of essential drugs, irrational combinations, and irrational drugs.

18 For National Health Policy (NHP), see <http://mohfw.nic.in/np2002.htm>

19 See Bhargava, Anurag in 'Pharmaceutical Policy (PP)2002 and National Health Policy (NHP) 2002: Discordance in Perspectives and Content', in LOCOST/JSS 2004, op.cit.

20 See: S.Srinivasan and T.Srikrishna. "Making Available Life-saving Drugs at Reasonable Prices: the Task Force Report". EPW, October 8, 2005

21 Quoted from: "The Strategic Approach", Executive Summary of the Report.

ABOUT ALL INDIA DRUG ACTION NETWORK (AIDAN)

All India Drug Action Network (AIDAN) is an independent network of several non government organizations, working to increase access and improve the rational use of essential medicines.

AIDAN is working towards a world where all people, especially the poor and disadvantaged are able to exercise their human right to health, which requires equitable access to affordable quality health care and essential medicines.

AIDAN and its partners recognize that poverty and social injustice are the greatest barriers to health and sustainable development. Partners are working for just societies where people can participate equitably in all decision making that affects their health and well being, including the allocation of resources.

AIDAN works:

- To promote the essential medicines concept, that fewer than 350 medicines are necessary to treat more than 90% of health problems requiring medicines.
- To increase access to these essential medicines and ensuring that they are available at affordable prices when treatment is needed, especially for the poor.
- For greater transparency in all aspects of decision making around pharmaceuticals, for example, by reducing industry secrecy and control over important clinical data.
- To promote the rational use of medicines: that all medicines marketed should meet real medical needs, have therapeutic advantages, be acceptably safe and offer value for money.
- For better controls on drug promotion and the provision of balanced, independent information for prescribers and consumers

For more details, refer: http://aidanindia.wordpress.com