Impoverishing the Poor : Pharmaceuticals and Drug Pricing in India

I did take the tonic, Sir !
But had to starve for days to buy it.

LOCOST/JSS, Vadodara, Bilaspur, India

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LOCOST/JSS
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September 2004

First Edition: January 2004
Second Edition: September 2004

This publication is brought out in public interest by Low Cost Standard Therapeutics (LOCOST), Vadodara, and Jan Swasthya Sahyog (JSS), Bilapsur, India.
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LOCOST is a non-profit trust based at Vadodara (Baroda), Gujarat, India. LOCOST produces good quality generics – about 80 drugs in all -- at low prices on a not for profit basis. People who use LOCOST drugs are NGOS and social action groups spread all over India and working with the poor. LOCOST founded in 1983 has been active in advocacy of a people-oriented drug policy and rational therapeutics (see also www.locostindia.com).

Jan Swasthya Sahyog is a team of health professionals, many of whom were trained at the All India Institute of Medical Sciences, New Delhi who are running a women health worker based community health program in 35 tribal forest-related villages of Bilaspur district of Chhattisgarh. Their actvities include running a community health centre based at village Ganiyari that provides low cost curative services to over 1000 villages of the district. Other activities of JSS include development of low-cost health related technology, field based action research on major public health problems, training and advocacy (see also www.geocities.com/jss_ganiyari/).

LOCOST and JSS are members of the All-India Drug Action Network (AIDAN). AIDAN was founded in 1982. AIDAN member-organisations have been active in the campaign for a rational, people-oriented drug policy. Members of JSS and LOCOST are also active in the Medico Friends Circle (MFC), an all-India network active since 1975 of socially concerned health action individuals, medical and health professionals and health researchers and academics from all over India (see also www.mfcindia.org)

Preface

We are happy that India can boast of a pharmaceutical industry that is one of the largest in the developing world. It has demonstrated the ability to provide low-cost but quality generic drugs for HIV and other diseases to the world outside and has the capacity to meet our entire drug needs. The Indian Patents Act 1970 ensured the growth of an indigenous pharmaceutical sector and the Drug Price Control Order protected the consumer from irrational drug prices. We would like the Government to safeguard the precious pharmaceutical sovereignty that we have won over the last three decades rather than sacrifice it at the altar of international agreements.

We would have been however happier if the conditions, which compelled the publication of this book, had not existed:

- if it were true that India were shining in the field of health
- if Indians really had access to the cheapest medications in the world
- had competition in the absence of regulation been the consumer's best friend in ensuring low prices
- had the drug industry, as much a knowledge-based industry as any other, had been able to unleash its creative potential for the benefit of the people
- if the national pharmaceutical policies, over the years, cared as much about public health as the profitability of the pharmaceutical sector.

The reality is very different and grim. Severe and growing inequities across classes and regions ensure that India's health indicators are anything but shining.

Drugs are overpriced and unaffordable – let there be no mistake about it, even though some of them may be 'cheapest' in the world. The margins are extremely high as we show in the following chapters. We even show that the same Indian drug companies, in an ironic twist, sell the same medicines cheaper in neighbouring Sri Lanka.

More 'players' have not resulted in lower prices of drugs in India or for that matter lower cost of health services. So what have the people of India gained by a world-class (or soon to be one) drug industry? Asking this question is as infuriating as asking why are many people going hungry to bed when our food godowns are overflowing and food stocks have to be destroyed every year.

Chaos Unbound

The Indian drug industry is the freest in the world in a wholly negative sense of the term. It is okay to conduct clinical trials of an anticancer drug with embryotoxic potential as an ovulation inducer in infertile women without permission. Consider some other facts:

- Hazardous drugs, long since banned in the rest of the world, continue to find place in our shops.
- Tonics of dubious therapeutic value abound that fritter away the patient's hard-earned money, leaving none to buy real medicines.
- Drug controllers in different states go on giving licenses to irrational preparations that add only cost but no value to the prescription.
- The Drug Controller of Karnataka (and it might be true of most other states) passes substandard drugs, looks the other way when violations of price control occur, and even collects bribes on a regular basis from his own subordinates.
- Nearly 40 children die of renal failure after consuming paracetamol syrup contaminated with ethylene glycol, the same substance that killed fourteen people in Mumbai twelve years ago, and this time too the drug-testing laboratory doesn't find anything amiss.
- Companies are free to set the margin of profits for themselves and the pharmaceutical trade. Doctors are free to prescribe medicines as they wish with no concern for indication, cost or rationality.
- The Medical Council of India and the Indian Medical Association cannot yet decide whether it is appropriate for a doctor to receive a car or an airline ticket or an air conditioner from a drug company. Chemists without the most elementary qualification are free to sell all kinds of drugs without a prescription.

Importance of Price Regulation

Price regulation in the pharmaceutical sector is an important instrument of public policy of promoting equity in access to health care. That instrument of policy is now being sought to be abandoned in the name of liberalization. The Pharmaceutical Policy (PP) 2002 of the Government of India wants to dilute drug price control – the last fig leaf of governmental concern -- by suggesting criteria for price control that will reduce the basket of price control to a bunch of irrelevant 30 or so drugs.

Which has good historical precedents: from 347 essential drugs in the late 1970s to seventy-four by the late nineties and now probably to around 30 if the 2002 policy is implemented. The kinds of drugs that would be left under price control are mostly irrelevant to public health. Even the Drug Price Control Order of 1995 conspicuously omitted drugs for anemia, diarrhoea, the majority of drugs for tuberculosis, hypertension and diabetes, and all drugs for cancer.

We have appended certain documents in the *Documents* section quoting chapter and verse literally from Government Committees that reinforce views expressed by the authors even as the PP 2002 tries to sing a different tune.

Hope in a New Government

It is hoped the new UPA government would examine the matter afresh and reformulates a new pharmaceutical policy that gives hope to poor Indians that they too matter. Indeed the Common Minimum Programme (CMP) of the new Government in the country says, inter alia, "the UPA Government will take all steps to ensure availability of life-saving drugs at reasonable prices. Special attention will be paid to the poorer sections in the matter of health care. The feasibility of reviving public sector units set up for the manufacture of critical bulk drugs will be re-examined so as to bring down and keep a check on prices of drugs."

The new Government must mean business and see wisdom in keeping essential drugs outside the vagaries of market forces and vested interests. It would be in good company if it indeed did so. Price control and/or some form of strict regulation of drug prices are the norm in all developing countries (with the possible exception of the USA).

Context of this Publication

The immediate context of the booklet is the case pending in the Supreme Court in which LOCOST, Jana Swasthya Sahyog (JSS), All India Drug Action Network (AIDAN) and the Medico Friend Circle (mfc) are co-petitioners. We have filed a series of affidavits in the matter[1] questioning the wisdom of the criteria for drug price control in Pharmaceutical Policy 2002 (PP 02). It is our submission that the policy will increase the price of medicines and therefore have a long-term effect, for the worse, on the health of people, especially poor people. The related SC order of 10/3/2003 says, "… We direct that the petitioner shall consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control..."

This litigation is also occurring at a critical juncture where India's state of public health is still grappling with old diseases while new ones like HIV/AIDS, diabetes and cardiovascular problems have got added on to the disease burden. Complicating this issue is the impending regime of WTO/TRIPS effective Jan 2005.

While final hearings are slated for sometime later in the year 2004, we felt it necessary to share with the wider public the grave issues in the matter affecting all people in India. These issues stand whatever be the outcome of the litigation.

This publication addresses pricing and related issues of the drug industry in India. It draws upon the experiences and insights of people, who have, over the past 25 years,

[1] Namely SLP(C) 3668/2003 filed by Union of India asking for impugnment of the order of the Karnataka High Court dated 12.11.02. The latter order (in WP No 21618/2002 Lt Col (Retd) Gopinath and another versus the UOI) stayed the operation of that part of the Pharmaceutical Policy 2002 that affected drug price control.

consistently engaged the government to ensure access to less expensive, safer, and more rational medicines.

We hope that it would enlarge the circle of public-spirited individuals and organisations that are concerned about these issues and drive them to do something about it. In this sense, it is not a book. It is a plea for action to do something.

Acknowledgements

Authors (AB and SS) wish to acknowledge the support of Mira Shiva, C.Sathyamala, our co-petitioners, and our lawyer Colin Gonsalves and his team for continued and appropriate legal advice. We also wish to acknowledge the support and encouragement, direct and indirect, of Anant Phadke, P.K.Sarkar, Wishvas Rane, Sunil Kaul, Ravi D'Souza and many others in the health sector and in the print media.

AB specially wishes to acknowledge the cooperation, patience, and forbearance of his wife Dr Madhavi during the preparation of this material. AB also wishes to acknowledge the inputs of his colleagues at Jan Swasthya Sahayog (JSS), Drs Yogesh Jain, and Biswaroop Chatterjee for their inputs. Also the JSS team of Drs Raman Kataria, Pramod Upadhayaya, Madhuri Chatterjee, Anju Kataria and Rachana Jain for their comradeship, without which this work would not have been possible.

We thank Dr Chandra Gulhati, Editor, MIMS India, for contributing Chapter 3 and *mfc bulletin* for permission to reproduce the same. We have acknowledged sources wherever possible and inadvertent omissions in this regard are regretted and may be brought to our notice.

-SS and AB.

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Documents

Some Important Links

1) The 13th Model List of Essential Medicines
http://www.who.int/medicines/organization/par/edl/eml.shtml

2) Pharmaceutical Policy 2002 and previous drug price control policies at

http://www.nppaindia.nic.in/index1.html

4) National Essential Medicines List (NEML) 2003
http://www.expresspharmapulse.com/nedl.pdf

5) National Health Policy (NHP)
http://mohfw.nic.in/np2002.htm

6) **Approved L1 rates for the supply of Drugs & Medicines for the Period from 01-11-2003 to 31-03-2005**

http://www.tnmsc.com/system.htm

7) WHO site in drug Price Information with Links to Other Countries
http://www.who.int/medicines/organization/par/ipc/drugpriceinfo.shtml

8) International Drug Price Indicator Guide at
http://erc.msh.org/

9) Delhi Society for the Promotion of Rational Use of Drugs
http://www.dsprud.org

(Second cover and third cover)

PRAYER[2]

In the facts and circumstances, stated herein above, it is MOST RESPECTFULLY prayed that this Hon'ble Court may be pleased to:-

(A) To issue a writ of mandamus or any other appropriate order or direction directing for an order directing the Respondent No.1 (Union of India) to ensure that the medicines/ drugs set out in the National Essential Medicines List 2003 are available and at affordable prices for the poor by bringing all of them under price control.

(B) To issue a writ of mandamus or any other appropriate order or direction directing for an order quashing the Pharmaceutical Policy 2002 to the extent to which this policy is incompatible with the other reliefs claimed in this petition.

(C) To issue a writ of mandamus or any other appropriate order or direction directing for an order directing the Respondent No.1 to bring all drugs and formulations under a system of monitoring of their prices and affordability with a view to ensuring that even drugs/ medicines not on the National Essential Medicines List are also available at reasonable prices.

(D) To issue a writ of mandamus or any other appropriate order or direction directing for an order directing the Respondent No.1 to ensure that only safe, rational drugs and formulations whose efficacy is scientifically proven be permitted to be manufactured and marketed in India.

(E) To issue a writ of mandamus or any other appropriate order or direction directing for an order directing the Respondent No.1 to ban the manufacture, distribution and imports and exports of all irrational formulations which have no scientific validity, or violate the principles of rational therapeutics or which do not figure in internationally accepted pharmacoepia.

(F) To issue a writ of mandamus or any other appropriate order or direction directing for an order directing the Respondent No.1 to allow the manufacture and marketing of only those single ingredient formulations that are referred to in pharmacology textbooks.

(G) To issue a writ of mandamus or any other appropriate order or direction directing for an order directing the Respondent No.1 to set up a National

[2] *(Prayer of petitioners in the case filed by AIDAN and ors. versus Union of India in the Supreme Court – WP (Civil) 423/ 2003)*

Drug Authority in accordance with the recommendations of the Drug Policy of 1986 and 1994.

(H) To issue a writ of mandamus or any other appropriate order or direction directing for an order directing the Respondent No.1 to ensure that both branded and generic medicines in the market are of standard quality and manufactured according to Good Manufacturing Policies (GMP) and Good Laboratory Practices (GLP).

(I) To issue a writ of mandamus or any other appropriate order or direction directing for an order directing the Respondent No.1 to ensure that all medicines needed for important public health problems such as tuberculosis, malaria, leprosy, diabetes, hypertension, heart care, eye care and the like to be marketed only as generic preparations.

(J) To issue a writ of mandamus or any other appropriate order or direction directing for an order directing the respondents to ensure that unbiased and comprehensive information including the information relating to the comparative costs of medicines and the total treatment regimes be in the public domain and be made available to prescribers as well as patients.

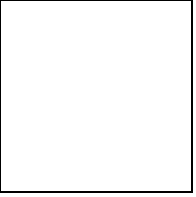
(K) To issue a writ of mandamus or any other appropriate order or direction directing for an order directing the respondents to set up an independent competent body to ensure that all new drugs introduced in the market from within India or abroad should be allowed in the country only if it meets the criteria of lower costs, better efficacy and less side effects, and after it undergoes testing in accordance with Schedule Y in the Drugs and Cosmetics Act.

(L) To issue a writ of mandamus or any other appropriate order or direction directing for an order directing the respondents to ensure access to newer, more efficacious and more affordable drugs post 2004, if necessary by using options such as compulsory licensing and parallel imports available under the WTO / TRIPS agreements.

(M) To issue a writ of mandamus or any other appropriate order or direction directing for an order directing the respondents to increase the health care budgetary allocations so as to realize the fundamental right to health care for all the people of India.

(N) Pass any other or further orders as may be deemed fit and proper in circumstances of the case.

(Prayer of petitioners in the case filed by AIDAN and ors. versus Union of India in the Supreme Court –WP (Civil) 423/ 2003)



CHAPTER 1

MISSING THE WOOD FOR THE TREES: DRUG PRICE CONTROL AND PHARMACEUTICAL POLICY 2002

-S.Srinivasan and T.Srikrishna

This chapter, now revised, was written in Sep 2003 when the threat of the Pharmaceutical Policy 2002 was imminent. However with the new Union Minister Paswan taking a more consumer-oriented stand, the threat has apparently receded for the time being. However the lobby for 'free trade and competition' and decontrol of prices is very strong though medicine prices may be controlled in even the so-called free market countries. This chapter and others in this book show that free competition, or what goes by its name, does not, in India, produce reductions in drug prices that benefit a majority of consumers. The successive policies of drug control in India since 1978 have resulted in decontrol of more and more of essential drugs and resulted in overpricing. Instead of balancing industry and user interests, and giving primacy to the patient when such a balance cannot be achieved, the PP 2002, like its immediate predecessors, is focused, on rolling out the red carpet for the pharma business in India.

1) Basis of Controls

Even as large Indian drug companies have even made international pharma majors rue about HIV/AIDS drug pricing in South Africa, the average poor Indian finds the costs of drugs unaffordable. For many, getting sick in India and buying medicines is a sure route to further impoverishment and penury[1]. Many people are forced to sell their cows,

[1] The Reserve bank of India (RBI) Rural Indebtedness survey of late eighties showed that amongst non-production loans healthcare was the first reason and amongst all loans it was the 2nd reason for indebtedness. The 52nd NSS Round on morbidity, utilizations and expenditure records indebtedness due to hospitalization. NSS 42nd and 52nd round and various other surveys show that between 15-40% of reported morbidities were unattended because of economic reasons. The Rural Labour Enquiry Report On General Characteristics Of Rural Labour Households (55th Round Of N.S.S.) 1999-2000 shows that men (women) on the average worked for 222 (122) wage days in a year and lost 31 (77) days in a year due to sickness. See http://labourbureau.nic.in/RLE992k%20GenChar%20Annex%20I.htm. The average earnings for all households for men ranged from Rs 40 to Rs 54 (Rs 28 to Rs 34 for women) and at least 25 percent of rural households were indebted at any point of time.

buffaloes and even homes whenever they try to access health services. Health care is the second leading cause of indebtedness in rural areas of India.[2]

Drugs are overpriced and unaffordable; margins are extremely high as we show below; and more "players" in the drug business has not resulted in lower prices of drugs.

And left to itself the pharma industry both in India (and the world) has shown little inclination to reduce prices voluntarily or make even essential drugs at affordable prices. It is for these reasons the Hathi Committee (1975) appointed by the Government of India recommended price controls and production controls. Underlying in the recommendation is the analysis that the market –free markets – are poor arbiters of the interests of the poor.

> **Bitter pill: Drug price control is an anomaly, says new NPPA chief**
>
> KGNARENDRANATH, TIMES NEWS NETWORK [FRIDAY, APRIL 09, 2004, 11:29:14 PM]
>
> NEW DELHI: There is reason for drug companies to cheer. Vinay Bansal, the new chairman of the National Pharmaceutical Pricing Authority (NPPA), is a firm believer in doing away with controls on prices of medicines.
>
> In an exclusive interview with ET, he stressed that price control on drugs was an anomaly that would eventually be removed altogether.
>
> "I have no doubt whatsoever that controlling prices of any commodity is an anomaly in a market-driven economy," Mr Bansal said. The chairman of the drug pricing body said this when his attention was drawn to the fact that price control has resulted in companies opting out of production and sale of controlled drugs, creating the problem of availability of important, and at times, irreplaceable medicines. "The government's twin objectives of ensuring availability and affordability of medicines can be mutually exclusive," the official, noted.

With such friends in the Government, who needs enemies?

2) Reduction of Price Control Basket of Drugs

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[2] For a contemporary journalistic reportage, see: P.Sainath's 'Anatomy of a Health Disaster', *The Hindu,* July 1, 2004 and 'The Poverty of Fiction,' in *Frontline,* Feb 28-Mar 12, 2004.

Price controls have been systematically reduced over the years (see Table 1 for *Comparative Chart Summarizing Price Control Scheme under Various Drug Price Control Orders*). This is because of a significant paradigm change among policy makers in their view of business and industry. It is now felt that controls – both production and price – discourage industry and therefore they should be cut down. Production controls have now mostly gone except for bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids, and specific cell/tissue targeted formulations. 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 drugs alone will remain under price control. (See Chapter 8, "Drugs Likely to go out of Price Control after PP 2002 and the ones Remaining")

Table 1: Comparative Chart Summarizing Price Control Scheme under Various Drug Price Control Orders

		DPCO 1979	DPCO 1987	DPCO 1995	Present Oct 2003
1	No of drugs under Price Control	347	142	76	74
2	No. of categories under which the above drugs were categorised	3	2	1	1
3	MAPE % allowed on normative/ National exfactory costs to meet Post-manufacturing expenses and to Provide for margin to the mfrs. Category I Category II Category III (Single ingredient Leader products)	 40% 55% 100 %	 75% 100% N.A.	 100% N.A. N.A.	 100 %
4	Total Domestic pharma sales covered under Price-Control (Approx)	90 %	70 %	50 %	36 % (?)

N.A. = Not Applicable

But as we will argue and show below that this is going to the other extreme and has had, and will have, deleterious effects on let alone the poor, but even the middle class of India.

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. Whereas Indian policy makers are intent on throwing out the baby with the drug price control basket.

3) Competition doesn't always lead to lowered prices[3]

The basic premise of removing price controls has been that competition will lower prices and that a free market exists now that we are in a post-liberalisation era, at least more free compared to earlier times. For example the document **Modifications in Drug Policy 1986** had this criteria: "Drugs in which there is sufficient market competition viz. at least 5 bulk drug producers and at least 10 formulators and none having more than the 40% market share in the Retail Trade (as per ORG) may be kept outside the price control."

In reality prices of drugs have been constantly on the rise[4].

There is no free market operating in the area of medicines, in pharmaceutical industry and in health and hospital services sector. The buyer/end user namely the patient has no choice. Informed choice involving techno-scientific issues is not possible for the lay consumer. The doctor/prescriber instead makes the choice for the consumer. The consumer has no easy way of evaluating doctor's prescriptions and advice. Both these assumptions – of a free market and that of competition reducing prices – are contestable.

Table 2 gives further justification of our assertion of weak and imperfect competition. If we go through the column on market share it shows that for most of the products, around 40 – 50 % of the market share is cornered by the leading 3-4 products. This happens in almost all the products. All the drugs mentioned in the table are antibiotics and antibacterials of one kind or the other. All but one namely cephataxime will be out of price control as per PP 2002.

In all these (in Table 2) we find that the top-selling brand of a particular category often is also the higher priced and most of the times the highest priced. The brand leader is also the price leader. If true competition and free market characteristics were present, the brand leader, that is the top selling would almost always sell at the lowest prices. The conclusion to be drawn is that competition does not always work in pharmaceuticals in the retail market in bringing down the prices, especially when there are many players, and therefore price control is necessary. Competition seems to work in bringing the price of the monopoly producer in the early stages of the product life cycle of a drug formulation.

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[3] See the accompanying chapter in this volume: 'Pharma Pricing in India: a failure of the Market (s)?'

[4] See for example the article "Continuing Rise in Drug Prices- Brand Leaders Show the Way" by Wishvas Rane, *Economic and Political Weekly*, July 24-30, 1999. Also see Rane's "Have Drug Prices Fallen?". *Economic and Political Weekly,* November 1, 2003)

But when the company knows that the sensibilities of the consumer/patient can be played upon, then the same drugs are priced to attract the high-end consumer.

For competition to work, a referee is needed in the form of an efficient regulatory agency with teeth – an agency that responds to market signals with alacrity. (The fact that competition does not lead, necessarily, to lowered prices in the pharma sector has been acknowledged by no less than a former chairperson of the National Pharmaceutical Pricing Authority, Mr Arun Kumar. See interview with Shri Arun Kumar, *The Economic Times, Sept 5, 2000*.)

Considering the pharmaceutical market, where the products – many a time - determine life and death, it becomes imperative that a different kind of 'marketing' structure be prevalent, keeping in mind that high cost often means a choice between living and dying.

We believe that even though marketing creativity in the market should be rewarded, it should not be unreasonable to the extent that the inefficiencies and marketing overheads of the market leader be rubbed off on to the consumer. For that is what we are doing when we legitimise a higher price of a brand: reward a company for its inefficiency and inability to sell at a lower price thereby increasing the costs of health care.

Table 2: Antibiotic Brand Leaders, Market Share and Price Behavior: A Brief Overview

Drug Product	Market Turnover of Product in Rs crores	Brand Name of Product Leader (s)	Market Share of Product Leader (in %)	Product Leader is Price Leader ?	Remarks
Cefataxime Injection	122.02	Taxim	63%	Yes	
Ceftrioxone Injection	136.01	Monocef	35 %	No	Price Leader is Becef
Cefuroxime Tablets	12.82	Ceftum	38 %	Yes	
Cephalexin Capsules	171.26	Phexin	69 %	No	Price Leader Ceff is 10 % more costlier
		Sporidex		No	
Amoxycillin Capsules	212.45	Mox	47 %	Yes	
		Novamox		Yes	
Amikacin Sulphate Inj	69.12	Mikacin	68 %	No	
		Amicin		No	
Chloramphenicol Capsules	41.31	Chlormycetin	86 %	Yes	Chloromycetin is the costliest
		Enteromycetin		Yes	
		Paraxin		Yes	
		Kemicetine		Yes	
Ampicillin + Cloxacillin Caps	109.05	Megapen	78 %	No	
		Ampoxin		No	
Ciprofloxacin Capsules	272.35	Cifran	56 %	Yes	Four brands dominate the market; the product is costly; but still would not be in price control as per PP 2002. Currently in price control.
		Ciplox		Yes	
		Ciprobid		Yes	
		Alcipro		Yes	
Doxycycline Capsules	63.35	Microdox	46 %	Yes	
		Doxy - 1		Yes	
Roxithromycin Capsules	97.60	Roxid	49 %	Yes	

Erythromycin Tablets	95.41	Althrocin	84 %	Yes	
		Erythrocin		No	
Azithromycin	62.71	Azithral	30 %	Yes	
Norfloxacin Tablets	53.09	Norflox	61 %	Yes	
Gentamycin	38.08	Genticyn	33 %	Yes	

(All data as per ORG-AC Nielsen Retail Audit, Oct 2003)

4) Overpricing of 5000 percent and more

Bids for tender prices one knows are severely competed for and the prices quoted can be taken as benchmarks for the lowest possible prices – as no manufacturer will supply drugs at a loss. Therefore a comparison of these prices with retail market prices will clearly give an idea of the amount of overpricing, or value added, or post-manufacturing margins. Comparisons of the tender prices quoted for the well-regulated, quality conscious, transparent Tamil Nadu Medical Services Corporation (TNMSC) shows estimated overpricing, or post-manufacturing markup, to the extent of 5000 percent. See below, Table 2 " A Comparison of Tender Rates and Retail Market Rates" [5] . *TNMSC has a good quality check system for anybody wondering how these drugs can be made and marketed at such low costs. From the authors' experience of low cost medicine production, we can say with confidence that these prices are feasible and possible.*

The prices given in Table 3 are for the strip/blister packs and price of bulk packs are even lower. Some comparisons of prices of LOCOST Baroda, a not for profit public trust making medicines and market prices are given below (Table 4). LOCOST does not give trade margins, as its sales are direct to those who are working on the field. Again this indicates the scope for the amount of profit and trade margins. In the table below, manufacturers can and give generics at the lowest possible price to the trade but often price it with high margins (MRPs). (See also P A Francis. 'High Profiteering In Generics', *Pharmabiz, Editorial, September 20, 2000.* The latest successful bids of TNMSC - Approved L1 Rates for the Supply of Drugs & Medicines for the Period from 01-11-2003 to 31-03-2005 - are available at http://www.tnmsc.com/system.htm).

[5] See also Srinivasan, S. "How Many Aspirins to the Rupee? Runaway Drug Prices", *Economic and Political Weekly, February 27-March 5, 1999*

Table 3: A Comparison of Tender Rates and Retail Market Rates							
Drug Name (1)	Name of Firm (2)	Tender Rate (Rs) (3)	Unit (4)	Mfr. (5)	Retail Market Price (Rs) (6)	Over-price Index Col (6)/(3): (7)	Tender Rate as percent of Retail Mkt. Price (8)
Albendazole Tab IP 400 mg	Cadila Pharmaceuticals P Ltd	22.60	10×10 tablets	Torrent	1190	52.65	1.89
Bisacodyl Tab IP 5 mg	Lark Laboratories (I) Ltd	16.50	10×10 tablets	German Remedies	717	43.45	2.30
Alprazolam Tab IP 0.5 mg	Bal Pharma Ltd	3.50	10×10 tablets	Sun Pharma	141.5	40.43	2.47
Diazepam Tab IP 5 mg	Pharmafabricon/LOCOST	3.05	10×10 tablets	Ranbaxy	92.5	30.33	6.26
Folic acid and Ferrous Tab NFI	Aurochem India P Ltd	5.89	10×10 tablets	Smith Kline	148.5	25.21	3.97
Amylodipine Tab 2.5 mg	Lark Laboratories (I) Ltd	9.10	10×10 tablets	Lyka	148.5	16.32	6.13

Adapted from: Srinivasan, S. "How Many Aspirins to the Rupee? Runaway Drug Prices", *Economic and Political Weekly*, February 27-March 5, 1999.

Table 4: Shocking Margins - A Sample Comparison of Generic Medicine Prices and Retail Prices

No	NAME OF DRUG	Strength	USE	LOCOST, Baroda Price June-Sep 2003	MRP of Standard Company as per DRUG TODAY April-June 2003
1.	Albendazole Tabs	400 mg	Against worm infestation	Rs 11.00 per strip of 10 Tabs	Rs 9.00 per Tab (strip of 1 Tab)
2.	Amlodipine Tabs	5 mg	Anti hyper-tensive (for high BP)	Rs 2.50 per strip of 10 Tabs	Rs 21.77 per strip of 10 Tabs
3	Amoxycillin Capsules	500 mg	Antibiotic	Rs 19.75 per strip of 10 Tabs	Rs 68.60 per strip of 10 Caps
4	Atenolol Tablets	50 mg	Anti hypertensive (for high BP)	Rs 2.80 per strip of 14 Tabs	Rs 20.00 per strip of 14 Tabs
5	Enalapril Maleate	5 mg	Anti hypertensive (for high BP)	Rs 3.00 per strip of 10 Tabs	Rs 22.58 per strip of 10 Tabs
6	Fluconazole Capsules	150 mg	Antifungal	Rs 35.00 per strip of 10 Caps	Rs 29.50 per caps (Strip of 1 Cap)
7	Glibenclamide Tablets IP	5 mg	Anti diabetic	Rs 1.50 per strip of 10 Tabs	Rs 3.73 per strip of 10 Tabs
8	Metformin Tablets	500 mg	Anti diabetic	Rs 3.00 per strip of 10 Tabs	Rs 6.45 per Strip of 10 Tabs
9	Paracetamol Tabs – 500 mg	500 mg	Fever reducing	Rs 2.00 per strip of 10 Tabs	Rs 6.90 per strip of 10 Tabs
10	Rifampicin Capsules	450 mg	Anti TB	Rs 32.00 per strip of 10 Caps	Rs 59.12 per strip of 10 Caps.

*** - from LOCOST Price List (Jun – Sep 2003)
*** - from DRUG TODAY (April - Jun 203)

4) Same Drug: Different Prices in the Market[6]

4.1 The same drug is available at different prices in the market. Given below are examples of three commonly used drugs: amlodipine, an antihypertensive; and antibiotics, ceftriaxone and ciproflaxacin. (See Chapter 3 for more discussion on this trend).

In the case of amlodipine the table below shows a 862% difference between the cheapest and the costliest in a drug with at least 40 formulators. The multinational has the drug with the maximum price. See Table 5.1 below.

In the case of Inj. Ceftriaxone, there is a 326 % between drugs (see Table 5.2). And in the case of the commonly used antibiotic, ciproflaxacin (a drug originally under price control and subsequently the subject of a dispute between the pharmaceuticals and the government, with the case being decided in the Supreme Court in August 2003 in favour of the Government of India.), the price difference is atleast 218 percent out of a total of 87 Brands listed in CIMS (see Table 5.3).

Table 5.1: Different Prices of Amlodipine

Drug	Brand name	Company	Price per tab. of 5 mg*
Amlodipine 5 mg.	Amlogard	Pfizer	Rs. 4.81
Amlodipine 5 mg.	Stamlo	Dr. Reddy's	Rs. 2.47
Amlodipine 5 mg.	Amlogen	Alkem	Rs. 1.20
Amlodipine 5 mg.	Amlodac	Alidac	Rs. 0.50

Source of prices: April-June 2002 edition of CIMS

Table 5.2: Different Prices of Inj. Ceftriaxone.

Drug	Brand name	Company	Price per 1g*.
Inj.Ceftriaxone	Cefaxone	Lupin	Rs.213.
Inj.Ceftriaxone	Oframax	Ranbaxy	Rs. 99
Inj.Ceftriaxone	Gutencef	E-merck	Rs. 50

All prices are as mentioned in the April-June 2002 edition of CIMS:

[6] The authors are grateful to Dr Anurag Bhargav of JSS, Bilaspur for the data presented in this section. See Chapter 2 for more on this trend of prices of drugs. See also Document 4 at the end of this booklet.

Table 5.3: A Comparison of the Leading Brands of Ciprofloxacin Listed in CIMS

Brand	Strength of tablet	Price* per 10 tablets	Company	Price of Cifran compared to the drug
Cifran	500 mg	85.34	Ranbaxy	
Ciplox	500 mg	78.90	Cipla	+8 %
Ciproace	500 mg	63.00	Ranbaxy	+35 %
Ciprolet	500 mg	49.50	Dr. Reddy's	+72 %
Strox	500 mg	39.00	Dabur	+118%
Zoxan	500 mg	29.00	Fdc	+194%
Orpic	500 mg	26.81	Dey's	+218 %

Source of prices: April-June 2002, CIMS

4.2 A study published by Roy and Rewari in the Indian *Journal of Pharmacology*[7] that surveyed the variation in prices of 84 formulations used in the management of cardiovascular diseases in the Indian market concluded that variation in prices ranged from 2.8 % to 3406 %. "In the absence of comparative information on drug prices and their quality it is difficult for physicians to prescribe the most economical treatment. There is an urgent need to provide adequate information to physicians regarding cost, bioequivalence and quality of drugs."

5) Same Drug, Same Company, Different Price

Why does the same drug company price the same drug under different brand names at different prices?

For example cefuroxime tablets are manufactured by GSK under the brand names of CEFTUM and SUPACEF at widely different prices - Rs 80.91 and 63.01 respectively for 125 mg tablets and Rs 150.34 and 144.94 respectively for 250 mg tablets.

Similarly ciprofloxacin 250 mg Tablets are manufactured by LUPIN under the brand names of CIPROVA and LUCIPRO 250 at the widely different rates of 41.79 and Rs 31.62 respectively.

Another example is of gentamycin Injection by PCI. It sells them as G-Mycin and Gentasporin at Rs 6.80 and 7.68 respectively.

[7] V.Roy, S. Rewari (1998). "Ambiguous Drug Pricing: A Physician's Dilemma". *Indian Journal of Pharmacology*, 30: 404-407.

For a marketing person, it is very clear and logical to "position" one consumer item – maybe a shampoo or toilet soap -- for the richer consumer and one for the less affluent. But try telling that to your average, busy, prescriber who does not have time to understand marketing techniques or try telling that to the poor patient. The ordinary person always believes as his/her doctor that the costlier version of the same drug is somehow therapeutically more effective. And if he/she cannot afford the costlier version, it is one's bad luck to have an "inferior" treatment.

6) Price Control is the Norm Even in the "Developed" World

Price Control is the norm all over the world except the USA which unfortunately India is trying to emulate[8]. Even in the 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[9].

One in three non-elderly Americans -- 74.7 million Americans -- were without health coverage for all or part of 2001-2002[10].

6.1 PPRS in UK

The UK has its Pharmaceutical Price Regulation Scheme[11]. The U.K. Pharmaceutical Price Regulation Scheme (PPRS) regulates profits to a band of 17–21 percent on historical capital, with 25 percent variation on either side. Companies are free to set prices, provided their rate of return is within these bands. If profits are higher, the company has to reimburse the National Health Service (NHS) or reduce profits the next year. If profits are lower, the company can raise its prices.

6.2 EU Countries

> "All EU countries, other than UK which has the PBS, 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. In Belgium, France, and Italy prices

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[8] See Documents 1 and 2 at the end of this booklet for a review of a visit by the DPCRC to several countries to study their drug pricing systems.

[9] See **"**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 http://www.familiesusa.org/site/PageServer?pagename=Media_Out_of_Bounds, July 9, 2003)

[10] See http://www.familiesusa.org/site/DocServer/Going_without_report.pdf?docID=273

[11] See http://www.doh.gov.uk/pprs/index.htm

> are set in relation to relative cost, prices elsewhere in the EU, and the contribution made to the national economy. In some countries (such as 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.

Elsewhere, and specifically, Canada has had its Patented Medicines Prices Review Board, France has its Transparency Commission and Economic Committee on Medicines, Egypt has all drugs under price control, Italy has restricted wholesale margins, Germany has its reference pricing system, and some system of price monitoring and price regulation prevails in Japan, Netherlands, China, Indonesia, Colombia and so on. In some of these countries drug pricing is tied with national health system reimbursements and or insurance schemes. In the absence of either in India, the havoc on the majority of the population can well be imagined.[12]

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[12] 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

The above facts have been noted, or ought to have been noted, by the appropriate policy making authorities in the Government of India. As a preparation to the Pharmaceutical Policy 2002, the Government of India had appointed the Drug Price Control Review Committee (DPCRC). The members of the committee visited various countries like the US, Mexico, Canada, France and Egypt. They also reviewed price mechanisms of Italy, Germany, Japan, the UK, Spain, the Netherlands, Switzerland, Indonesia, Colombia among others. What they found was contrary to popular expectations. *There is no free market pricing in drugs even in the so-called free market economy countries.*

The Committee report[13] observes at one point, "Marketing approval for every drug whether imported or indigenously manufactured and registering them with the appropriate government authority has been accepted as a fundamental requirement for every pharmaceutical product. Countries have adopted the system of reimbursement pricing, reference pricing, patented product pricing, etc, in order to put a moratorium on the prices of pharmaceutical products that can be charged. In some countries, a cap has been put on the margins allowed to the wholesalers and pharmacists...In others, registration of prices is insisted at the time of seeking marketing approval. Further, there are various systems of ensuring reasonable health cover either by the public funded programmes or through the private companies in the health and insurance sectors."

Let us quote further from the summary recommendations of the said committee:

> *... 2 The Committee noted that 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 drugs 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.*
>
> *3 In India, in view of a large segment of the population being poor, the reach of the health coverage being inadequate, non-availability of appropriate medical insurance coverage, price inelastic demand, market imperfections and inadequate consumer awareness, the Committee considers it necessary to continue formal regulation of the prices of pharmaceutical products and medicines for some more time till public expenditure on health care for those*

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

[13] See Document 1 for the relevant detailed extracts from the DPCRC Report.

> *who cannot afford is increased and an alternative system is developed for others. However, it is pertinent to point out that the pharmaceutical industry is perhaps the only knowledge-based and highly technology-oriented manufacturing industry in the country which is under a formal price control regime. This is mainly because the financial provisions in the budgets of central and the state governments are too inadequate to cater to the needs of the ailing people. The Committee expresses serious concern on this aspect and feels that the budgetary provision should progressively be raised. Further, there is an urgent need to expand public health care, supply of essential drugs and the health insurance cover, both by the governmental and the non-governmental organisations, as prevailing in the developed countries. Such an alternative arrangement should be made fully operative within a period of next five years.*
>
> *4 The present system of product-based price control has been in existence in this country since long with progressive decontrol in terms of the number of drugs as well as their share in the total pharma market. For the reasons stated above, the Committee is of the view that this system should continue, for the time being, but with simplified methodologies and procedures to take cognisance of the changed circumstances of liberalisation ushered into the Indian economy. For the purpose of determining span of control and pricing of the drugs identified for price control, the Committee recommends.*
>
> *The approach to price control based on selectivity be continued and applied across-the-board to all the drugs used in the country irrespective of their therapeutic use. The guiding factors to identify specific drugs should be (a) mass consumption nature of the drug and (b) absence of adequate competition in such drugs. This approach will also ensure that the important drugs needed for National Health Programmes, where adequate competition does not exist, are covered for the purposes of price control.* (emphasis ours)

It is clear that the Committee recommendations do not talk of wanting the price control to be wished away. It is also clear therefore that there ought to be no dismantling the NPPA and the useful work it does against odds. So why does the Government of India talk of reducing drugs under price control?

6.3 Cost-effectiveness controls: controls on new drug introduction

There has been a clamoring among Indian pharma industry that new drugs should not have any price controls. Especially drugs that are a result of Indian R & D are supposed to be exempt for 15 years. This blanket exemption while understandable from the point of view encouraging Indian R & D needs to be tempered with effects on poor end users. Similarly is the case of drugs that are imported. There needs to be a price control – the PP 2002 recommends a ceiling of 50 percent more than the landed price. What about transfer pricing? How do you ensure that it has not already been excessively billed? In any case how do we evaluate whether the new drug imported or a product of Indian R

and D, is really therapeutically necessary. For new drugs, the practice in EU and Australia includes the following:

> "Throughout the EU and elsewhere, there is increasing interest in complementing pharmaceutical licensing procedures with -- (that) -- of demonstrable cost-effectiveness. Although European economists have advocated such controls for several decades, Australia pioneered the approach nationally within its Pharmacy Benefits Scheme (PBS). Since 1999 the National Institute of Clinical Excellence (NICE) has issued guidance to the NHS in England. Both the PBS and NICE require companies to submit evidence of the costs and effects of new products. Recommendations are generally for specific subgroups of patients and are guided by cost-effectiveness and cost-utility analysis. Economic data are now used to inform reimbursement and pricing decisions in a number of EU states. Finland, Portugal, the Netherlands, France, Spain, and Sweden are all developing the use of such data in their regulatory systems."[14]

7) Misleading Drug Promotion: Cause of Drug Over Pricing

Probably among the important reasons why drugs are over priced are misleading drug promotions. The margins discussed above are used to give gifts, sponsor seminars, etc. to the medical profession. "Many US faculty members on institutional review boards have ties with industry" says a recent report in the British Medical Journal [BMJ 2003;327:414 (23 August)]. This clearly influences research outcomes – atleast in some cases. In India drug companies are known to give Maruti cars[15]. Sponsoring for holidays and medical seminars are now considered passe. Only the Indian Academy of Paediatrics among professional bodies has taken a principled stand on this matter by banning drug company sponsored conferences of its meetings.

Six good reasons to be concerned about drug promotion[16]

- Drug companies spend on average around 35% of sales on promotion.[1]
- Companies would not spend such massive amounts on promotion if it were not effective at influencing prescribing.

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[14]Source: Alan Maynard and Karen Bloor "Dilemmas in Regulation of the Market for Pharmaceuticals". *Health Affairs* ~ Volume 22, No.3, May-June 2003

[15] For other such instances, see Chapter 3 in this booklet as also 'Marketing of medicines in India: Informing, inducing or influencing?' by Dr. Chandra Gulhati, *BMJ* 2004; 328:778-779 (3 April). See also: *Surviving the Pharmaceutical Jungle* by Nobhojit Roy and Neha Madhiwalla, a new study on the unethical promotional practices of pharma companies in India. See the Jan-Mar 2004 of *Issues in Medical Ethics*. For the study see www.issuesinmedicalethics.org/docs/Pharmrpt.pdf

[16] Source: http://www.healthyskepticism.org/problem.htm
The references for the statements following are given in the text itself.

- Promotion influences prescribing much more than most health professionals realise.[2-5]
- Many advertisements and statements from pharmaceutical representatives are misleading.[6,7]
- Promotion which exaggerates benefits and glosses over risks, threatens optimal treatment.
- Reliance on promotional information may endanger lives and expose prescribers to the risk of litigation.[8]

1. *Devlin J, Hemsley P. Management views on industry issues, pressures and consultants. Scrip Magazine. 1997 June 16-183.*
2. *Caudill TS, Johnson MS, Rich EC, McKinney P. Physicians, pharmaceutical sales representatives and the cost of prescribing. Arch Fam Med 1996; 5:201-6*
3. *Orlowski JP, Wateska L. The effects of pharmaceutical firm enticements on physician prescribing patterns: There's no such thing as a free lunch. Chest 1992;102:270-73*
4. *Waud DR. Pharmaceutical promotions. New Engl J Med 1992;327:23:1688*
5. *Chren M-M, Landefeld CS. Physicians' behaviour and their interactions with drug companies: A controlled study of physicians who requested additions to a hospital drug formulary. JAMA 1994;271:9:684-9*
6. *Wilkes MS, Doblin BH, Shapiro MF. Pharmaceutical advertisements in leading medical journals: Experts' assessments. Ann Int Med 1992;116:912-919*
7. *Roughead EE. The pharmaceutical representative and medical practitioner encounter: implications for quality use of medicines. Masters Thesis. School of Health Systems Sciences. La Trobe University. Aug 1995*
8. *Aders HP. Legal liability and drug prescribing. Cur Therap 1991;32:6:17-21*

There are other undesirable practices which apart from harmful effects to the patient actually affects pricing – the consumer pays for it (see for a more detailed discussion *A Lay Person's Guide to Medicine: What is Behind Them and How to Use them,* LOCOST, Baroda, Dec 2000) The most reputed pharma companies of India – MNCs as well as national ones -- have been indicted at one time or the other. Recently the British Medical Journal [*BMJ* 2003;326:620 (22 March)] reported "Whistleblower charges drug company with **deceptive** practices" and gave the following details:

> A former drug company insider has spoken to reporters for the first time since he filed a whistleblower lawsuit in 1996 in a US federal court. ...The suit charges that Parke-Davis engaged in elaborate inducement schemes to persuade doctors to promote the off-label use of one of its best selling drugs, gabapentin (Neurontin), an anti-epileptic drug approved as adjunctive treatment for partial seizures. It also says the company ran ghost writing schemes, in which it paid specialists to "author" articles that were actually written by technical writers hired by the company.

Prescribing drugs off label accounts for over 78% of sales of gabapentin, according to Parke-Davis. Although off-label prescribing is legal, the US Food and Drug Administration prohibits drug companies from promoting such use to doctors. Parke-Davis, which was a division of Warner-Lambert when the promotional activities are alleged to have occurred, was acquired by Pfizer in 2000.

8) Problems with the Pharmaceutical Policy 2002, its Price Control Methodology and the ORG-MARG Retail Audit

8.1 *Price Control Criteria of PP 2002*

The Pharmaceutical Policy (PP) 2002 has this to say on the pricing methodology to be adopted:

> "The Department through NPPA, with the help of NIPER has developed the desired database for single ingredient formulations from the retail store audit data as published by ORG-MARG. On this basis, the Department proposes to undertake the exercise of identifying the bulk drugs of mass consumption nature and having absence of sufficient competition according to the following methodology:
>
> i. The 279 items appearing in the alphabetical list of Essential Drugs in the National Essential Drug List (1996) of the Ministry of Health and Family Welfare and the 173 items, which are considered important by that Ministry from the point of view of their use in various Health Programmes, in emergency care etc., with the exclusion., as in the past, therefrom of sera & vaccines, blood products, combinations etc. should form the total basket out of which selection of bulk drugs be made for price regulation.
>
> ii. The ORG-MARG data of March 2001 would form the basis for determining the span of price control as suggested by DPCRC.
>
> iii. The Moving Annual Total (MAT) value for any formulator in respect of any bulk drug will be arrived at by adding the MAT values of all his single-ingredient formulations of that bulk drug, its salts, esters, stereo-isomers and derivatives, covering all the strengths, dosage forms and pack sizes listed against that formulator in all groups / categories of the ORG-MARG (March 2001).
>
> iv. The MAT value for all the formulators, as defined in sub-para (iii) above, in respect of a particular bulk drug will be added to arrive at the total MAT value in the retail trade.
>
> v. The MAT value for an individual formulator, in respect of any bulk drug, as arrived at in sub-para (iii) above, will be the basis for

calculating the percentage share of that formulator in the total MAT value arrived at as in sub-para (iv) above, in respect of that bulk drug.

vi. Bulk Drugs will be kept under price regulation if:-

(a) The total MAT value, arrived at as in sub-para (iv) above, in respect of any particular bulk drug is more than Rs.2500 lakhs (Rs.25 Crore) and the percentage share, as defined in sub-para (v) above, of any of the formulators is 50% or more.
(b) The total MAT value, arrived at as in sub-para (iv) above, in respect of any particular bulk drug is less than Rs.2500 lakhs (Rs.25 Crore) but more than Rs.1000 lakhs (Rs.10 Crore) and the percentage share, as defined in sub-para (v) above, of any of the formulators is 90% or more.

All formulations containing a bulk drug as identified above, either individually or in combination with other bulk drugs, including those not identified for price control as bulk drug, will be under price control. The Government shall, however, retain the following over-riding power:

In cases of drugs/formulations listed by the Ministry of Health and Family Welfare, mentioned in sub-para (i) above, and those presently under price control, having significant MAT value as per ORG-MARG but not covered under the criteria in sub-para (vi) above, as a result of this proposal, the NPPA would specially monitor intensively their price movement and consumption pattern. If any unusual movement of prices is observed or brought to the notice of the NPPA, the Authority would work out the price in accordance with the relevant provisions of the price control order.

8.2 ***Inappropriateness of Policy Based on Single Ingredient Formulations***

The first point to be noted in the above criteria of PP 2002 is that it relies as the basis on the so-called retail store audit data, of ORG-MARG (now ORG-AC Nielsen, henceforth in this paper referred to as ORG), of single ingredient formulations only. This does not reflect reality at all as most (atleast 50 percent conservatively) of the market consists of combination or multi-ingredient formulations. Thus the very basis of the data is faulty.

Adding data of combination formulations as per PP 2002 will

- increase the possibility of the MAT of a drug going over Rs 25 crores or over Rs 10 crores.
- increase the possibility of the market share of a formulator going over 50 percent.

The said drug may have escaped price control otherwise. On the other hand it could diffuse the market shares, say as in the antibiotic formulations category, and a company may have unfairly - unfair in terms of criteria enumerated by PP 2002 – been earlier under price control.

The March 2001 ORG MAT figures of cloxacillin single ingredient drug is Rs 1.97 crores (about Rs 1.4 crores as per ORG Oct 2003) in which Lyka Labs has a share of 95 percent. Whereas cloxacillin is mostly sold in the market in combination along with Ampicillin (as in the brand name Ampiclox). The sale of Ampiclox combinations as per ORG Oct 2003 figures is Rs 147 crores. Current bulk drug prices would give a 50 percent value contribution of ampicillin to the ampiclox combination. Therefore the total sale of cloxacillin component would be atleast Rs 73.5 crores as compared to the sales figure of Rs 1.4 crores of the single ingredient. How accurate then is the PP 2002 price criteria? That this combination is irrational and unscientific is another issue which the PP 2002 is not concerned with at all. Cloxacillin is currently under price control but would escape price control as per the criteria of PP 2002. Ampicllin is not under price control now and would also escape price control if PP 2002 were in force.

We have other instances of drug combinations (see Table 6) with considerable market dominance that would escape price control because of the PP 2002 criteria because one the constituents are individually out of price control. This when any industry observer knows that if a brand has a sales turnover of Rs 1 crore and more, it has "arrived". We give examples.

Table 6: Sale of Single Ingredient Formulations vs. Combinations

)

Name of the Drug	Value of Single Ingredient Formulations alone	Value of Combinations alone
Cloxacillin	1.41	197.72
Norfloxacin	53.29	107.10
Metronidazole	27.28	99.09
Ciprofloxacin	284.28	94.79
Enalapril	79.64	22.04
Atenolol	123.63	176.40
Metformin	59.56	163.17

(All figures in rupees crores and as per ORG Oct 2003 retail audit)

The largest antibiotic molecule in terms of turnover (Oct 2003 ORG figures) is ciprofloxacin with a turnover of Rs.284 crores. There are 126 brands in the ciprofloxacin category, this would mean, one brand for every two companies that ORG audits. Only three brands, Cifran, Ciplox and Ciprobid have more than 50% of the share of this market and the rest 123 brands cover the remaining market.

The price of these brands of 250 mg capsules varies from Rs 14 to Rs 44 bringing us again to the point that looking at the vast differences in ciprofloxacin brand pricing, the leader is anyway "milking" the market. Should not these be under price control – but escape they will from price control as per PP 2002 criteria?

Another gross example is that of roxithromycin. The size of the market is Rs.97 crores (ORG Oct 2003 data) and there are 100 brands in the category. Only one brand Roxid has

a market share of 49%. Remaining 99 sharing the rest of the market. Will also escape price control as per PP 2002 criteria.

8.3 ***Mass Consumption and Price Control***

A high turnover of a commonly used drug like say paracetamol (brand name: Crocin, etc.) or an antibiotic like amoxycillin, or a very useful antibacterial like co-trimoxazole (brand name Septran, Bactrim, etc.) would sooner or later go out of the price control. Even on price controlled drugs generic manufacturers are giving today unprecedented margins. What will happen when a drug like paracetamol or aspirin (aspirin 75 mg is recommended as a preventive for heart attack) can well be imagined. The criteria of PP 2002 looks as if that a drug however essential, because of its mass consumption nature, will go out of price control can well be imagined leaving the market to bring down the prices. We have seen the market is a poor regulator in the matter of medicines. Precisely because a drug is useful, and essential, its price needs to be under control. But here it appears that precisely because a drug is useful -- it will be mass consumed, be available at different prices in different brands and may have a MAT of over Rs 25 crores and no formulator having more than 50 percent share – its probability of going out of price control increases.

8.4 We give other counter-examples.

a) MAT Value Rs 10-25 crores

A drug has Rs 10-25 crore MAT value but a formulator of the drug having even more than 50 % market share will escape price control. One can price it arbitrarily.

The irrational drug analgin, banned in several countries, has a MAT of Rs 23.95 crores and the leading brand Novalgin of Hoechst MR has a share of 57 percent.

Likewise, Hoechst has an 85.16 % market share of the peripheral vasodilator pentaxyfyline (MAT value as per ORG Mar 2001 Rs 12.80 crores). Not under price control as per PP 2002 criteria.

The case of Vitamin C is discussed independently below.

b) MAT Value Less than Rs 10 crores

In the situation under Rs 10 crores MAT value of a drug, one can be the only producer and still escape price control. However essential or life saving the drug maybe.

Take for example, the life-saving diuretic and antihypertensive (anti high BP), frusemide. Total MAT value of the drug (ORG March 2001) is Rs 9.48 crores and the leading brand Lasix of Aventis has a market share of over 97 percent. Just escapes price control and surely would have crossed the Rs 10 crores barrier since March 2001. This when the more useful and scientific diuretic, hydrochlorthiazide, is practically not

available in the market. Other examples in this category (under Rs 10 crores MAT and escaping price control inspite of practical monopoly) are levadopa used for antiparkinsonism, Ranbaxy has a share of 86 percent (ORG March 2001), Vitamin A, MAT Rs 8.56 crores and leading market shareholder USV has 80 percent share. Vitamin A incidentally has a monopoly bulk supplier (Roche) and is useful against night blindness. Cefazolin, antibiotic, priced at a range of prices (MAT Rs 4.22 crores, leading producer of formulation (injections mostly) has 96 percent share.

c) MAT Value Greater than Rs 25 Crores

Also when turnover is greater than Rs 25 crores, one can have 0 to 49 % market share; or three or more producers can each have less than 50 percent and they can escape price control.

We give the example of ranitidine, a leading antiulcer, antacid, to illustrate the point. Ranitidine has a MAT value of Rs 148.04 crores (ORG March 2001 figures) and Glaxo SKB and Cadilla Pharma together have a market share of 63.5 percent. It is a moot point that the drug price will not be cartelised but the price of the branded ranitidine 150 mg tabs varies between Rs 5 to Rs 12 per 10 tabs (CIMS July 2003) whereas the ex-factory price ought to be Rs 3.00 per 10 tabs (LOCOST, July 2003). Incidentally, there is an oligopoly of producers for the bulk drug ranitidine. Ranitidine is currently under price control and will go out of price control as per PP 2002 criteria.

The anti-diabetic Insulin has MAT of Rs 161.77 crores and three of the top brands has a market share of over 80 percent. It will go out of price control as per PP 2002. Insulins are highly priced. Ask any person with diabetes.

d) Decontrolled Essential Drugs, High Price, High Variation

Many crucial, essential drugs say for cancer, may or may not fall in the price control criteria but they show a wide range in pricing and are very costly if bought from particular companies. For example: Khandelwal sells tamoxifen 10 mg, used by breast cancer patients, for Rs 29.21 for 10 tablets. It is also sold by ICI at Rs 951 for pack of 50 tablets (that is Rs 95 or 10 tablets). And Nicholas sells 50 tablets for Rs 1388 (that is Rs 277.60 for 10 tablets). So if you are a traumatised patient with mastectomy performed on you and trying to recover, you will be racked with doubt which brand to take and probably settle in for the costlier version. Some doctors will recommend costlier versions because they too believe a costlier tablet of the same drug would have better quality and efficacy. Similar is the case of flucanozole 150 mg (antifungal also useful in Anti AIDS treatments): the prices vary from Rs 3.50 to Rs 30 per tablet. (All prices as per *MIMS* July 2003 and *Drug Today* July-September 2003).

e) No Rationale between Price and Drug Presentation

A drug may be out of price control - or in a particular formulation may be under control. But there is seldom any rational in pricing between its tablet presentation and its

presentation as an infusion. For instance ofloxacin, a currently popular antibiotic, costs Rs 3 to Rs 4 per tablet of 200 mg but its infusion may cost anywhere between Rs 30/- to Rs 60/-. Price controls normally focus on the more popular versions. But infusions inasmuch as they are misused, are useful in critical conditions. So if one is critical, he/she has to needlessly pay more if an infusion is needed. Many drugs out of price control with several players in the market but critical otherwise have a range of pricing as already pointed out.

The situation with respect to new drugs third generation and fourth generation antibiotics/cephalosporins is alarming. The prices are very high even for single units.

As for vital and life-saving drugs which have escaped price control because of other previous criteria (say that of Drug Policy 1995), as we have already shown above that there is an unreasonable variation in price of branded formulations based on the same bulk drug from 200 to over 2000 percent. And more.

f) What of Drugs not in the Price Control Basket?

The PP 2002 says that the basket of 279 drugs (see para 8.1 above) will be the pool from which the MAT criteria would be applied to decide which drugs would be on price control or would be out of it. But as an accompanying chapter in this book shows 70 percent of the top-selling 300 drugs are irrational – how about price control on these? And do we not need to consider the deleterious effects of overpricing on the many of the 20,000 formulations which fall out of price control, made usually by small scale companies (which are out of the ambit of price control)? Not to mention the burgeoning market of overpriced ayurvedic/herbal formulations and the so-called nutraceuticals – which are overpriced and mostly inappropriately prescribed by doctors as diet supplements for the sick, convalescing and the healthy.

8.4 ***Inappropriateness of Bulk Drug Price Control Criteria***

The PP 2002 criteria are also faulty on the following grounds: MAT sales criteria are based on formulations based on ORG figures. Even if one accepts the soundness of the "Sufficient competition criteria" described in the PP Policy 2002 (quoted in Para 3 of Section 8.1 above), MAT sales figures of formulations decides which bulk drug will be in price control. Or out of it. A bulk drug may go out of price control, but it has nothing to do with whether there is competition among mfrs of the bulk drug in question. Thus a bulk drug may go out of price control even if it had one or 2 mfrs for it in the country. The Policy thus would lead to encouraging and legitimizing monopoly and oligopoly situations in the bulk drug segment of the Pharmaceutical market.

As an example, take the case of Vitamin C. According to ORG March 2001 figures it has a MAT of Rs 21 crores and GSKB (Glaxo) and Sarabhai Piramal have a total market share of 54 percent in Vitamin C formulations. Vitamin C formulations would would escape price control according to the criteria of PP 2002 and so would the bulk drug.

Vitamin C bulk drug has only two (at most three) producers in the country, with Sarabhai having a predominant share. One should add however that Vitamin C bulk drug has been independently under price control because it meets the criteria of price control of the earlier policy (see below). And the two lone Indian producers had complained to the government of dumping by foreign traders/ companies.

Contrast this to the concern shown in avoiding monopoly situations in bulk drug pricing in the "Modifications in Drug Policy", Para 22.7, of which states inter alia:

> The criterion of including drugs under price control will be the minimum annual turnover of Rs.400 lakhs. Drugs of popular use, in which there is a monopoly situation will be kept under price control. For this purpose if for any bulk drug, having an annual turnover of Rs. 100 lakhs or more there is a single formulator having 90% or more market share in the Retail Trade (as per ORG) a monopoly situation would be considered as existing.
>
> Drugs in which there is sufficient market competition viz. at least 5 bulk drug producers and at least 10 formulators and none having more than the 40% market share in the Retail Trade (as per ORG) may be kept outside the price control. However, a strict watch would be kept on the movement of prices as it is expected that their prices would forces of market competition. The Government may determine the ceiling levels beyond, which would not be permissible. *(emphasis ours)*

8.5 ***Irrelevance of Essentiality of Drugs for Price Control***

The criteria of PP 2002 have little to do with essentiality and vitality of drugs. No convergence with health policy, disease profile, health situation of the country, availability of health care and pricing of drugs. For example, none of the HIV/AIDS drugs, which are high-priced, will come under price control as per the criteria.

No importance is given to the therapeutic importance of the drug, its importance in the national programmes, its importance in dealing with critical ailments and their complications arising out of the field level realities. Pure economics and trade figures are a blind way to identify drugs for price control. For instance TB, a national killer, often routinely leads to complications because of non-compliance of treatment regimes by patients, either because of non-availability of drugs when needed or non-affordability, or remote location of the TB patient, etc. and thereby developing resistance to first line drugs. In such cases second line or third line drugs for TB have to be resorted to. Second line TB drugs are not under price control. Why are second line drugs not sold enough to fall under the PP 2002 criteria of price control? Because as yet most doctors persist with first line drugs and possibly the patient is dead by the time somebody in the health system notices him/her to give second line drugs.

8.6 ***Is there an Appropriate Price Control Criterion?***

We however need to stress that despite our critique of the criteria of PP 2002, similar remarks would be due for the criteria under the earlier 1995 policy "Modifications in Drug Policy" – a part of which is quoted in para 8.4 above. Purely turnover-based criteria would always tend to miss out the wood for the trees: that is, would decontrol many essential drugs and have not so critical drugs under price control. Only criteria that integrate the vision of affordability in the context of health seeking behaviour of our people would make reasonable sense. One way is to have always have essentials under control and go by turnover criteria for inessentials, short of weeding out inessentials totally. Another option is to give essentials reasonable margin of profit and give non-essentials say 50 percent post-manufacturing markup.

However the least messy, scientifically most rational and administratively elegant way of price criteria for formulations is to do what the Bangladesh Drug Policy has done successfully since 1982: only a limited list of essential drugs are to be manufactured in the country, and the MRP for tablet formulations is kept at 100 percent more than the cost of the raw material content in the tablet and for capsules 125 percent more than the cost of the raw material content; and manufacture of liquid formulations (normally the ones that are misprescribed in the form of vitamin and nutrient tonics) are to be strictly restricted.

8.7 ***PP 2002 and Taxation/Duty Norms***

The PP 2002 does not talk of giving fiscal incentives for drug production of let alone essentials and generics but at least for those belonging to the National Disease Programmes. The aggregate tax component on drugs (including excise duty and central sales tax) is about 30 per cent at present. Today the government has no systematic policy of collecting excise on essential, life saving drugs. Exemptions are given on strengths of lobbies. All anti-AIDS drugs are now exempt from sales tax and excise duty. Rifampicin, a crucial drug against TB, is levied excise of 16 %, but there is no CST and no sales tax in Gujarat but sales tax is levied in Assam. The anti malarial chloroquine has no excise duty but has CST and Gujarat Sales Tax. Ethambutol, INH, pyrazinamide - all used against TB and leprosy are exempt from CST and excise duty. ORS (oral rehydration salt) is levied excise. ORS is also curiously not in price control despite it being a vital aid in the management of diarrhea and despite it being available at widely differential prices.

8.8 ***NPPA and Lack of Transparent Methodology***

In cases where drugs that have escaped price control are still found to be highly overpriced, the criteria, or for that matter the monitoring agency of the government, National Pharmaceutical Pricing Authority (NPPA), has no transparent methodology to identify/monitor drugs to be put under price control. Given the proliferation of branded formulations, atleast 100,000 (one lakh) in number, it is difficult to see how prices of drugs out of the price control can be monitored in an effective and efficient manner. In fact it has not been able to do so and a result we have the formulations based on the same

bulk drug sold at vastly different prices. The Drug Price Control Review Committee (DPCRC) report has also pointed out this gross distortion and a problem (see Tables 5.4 and 5.5 of DPCRC report as well as section on 'Monitoring of Prices' in Chapter 5 on "Pricing of Drugs", pp.61 –62) of the same report. At another level, the NPPA relies on ORG retail audit data which itself cannot be said to be in the public domain. They are expensive and accessible only at a price to the public (the complete ORG retail audit report for any year is priced at Rs 15 lakhs).

8.9 ***Observation of Govt. Committees: Price Control***

Nowhere in the world are drugs free of price control as has been pointed out already. A fact also mentioned in detail in the DPRC (Drug Price Review Committee, October 1999, Chapter 3, pp 23 ff)) report as well as in Chapter VI of the 15th Report (August 2001) of the Parliamentary Standing Committee on Petroleum and Chemicals (13th Lok Sabha) on "Pricing and Availability of Drugs and Pharmaceuticals". (Extracts reproduced as Document 2 in the "Documents" section.)

8.10 ***Observation of Govt. Committees: Huge Trade Margins***

The problem of huge margins to the trade (more than 1000 to 3000 percent) of drugs out of price control has not been addressed by the Pharmaceutical Policy of 2002. In fact it is a failure of the principles on which drugs have been kept out of price control. This fact has also been noted by the DPCRC [Chapter VI, Summary and Recommendations, 11 (vii)]:

> "It has also been observed that some of the manufacturers tend to provide unduly high trade margins, adversely affecting the consumer interest. Therefore, the committee is of the view that to discourage unethical practices by the players, the difference between the first sale price of a formulation by the manufacturers and the retail price printed on the label be limited to a maximum of 40 percent of the MRP in the case of decontrolled formulations."

We have similar observations from the 15th Report (August 2001)of the Parliamentary Standing Committee on Petroleum and Chemicals (13th Lok Sabha) on "Pricing and Availability of Drugs and Pharmaceuticals", Part II, Recommendations and Conclusions of the Committee, para 26:

> The committee find several lacunae the price control fixation system of NPPA. NPPA fix the price of bulk drugs on the basis of data provided by the manufacturers. Although the prices of some bulk drugs have moved down, this is not reflected in the retail prices of non-scheduled formulations. Besides, concern has been expressed on the high commission / margin offered to the trade, much detriment of the consumers. The Committee desire that the different between the

> first sale price of a formulation by manufacturers and the retail price be limited to a specific level say one third of the first sale price of the maximum retail price in the case of decontrolled drugs. Price control system should encourage use of time-tested effective/safe drugs and to discourage the use of costly drugs which may not be medically superior. Involvement of Drug Controllers at the time of clinical tests may prove beneficial. (emphasis authors')

The remarks of the Committees are slightly inaccuarate. The margins are even more – see Table 7, *Extent of Trade Margins: Some Examples*, for instance. These are margins only from the distributor to the retailer. The actual margins in the entire trade from manufacturer to retailer are likely to be even higher.

Table 7: Extent of Trade Margins - Some Examples [17]

(All prices in rupees)

Sr. No.	Brand Name	Content (s)	Manufacturer	Use	Packing Unit	Distributor's Price	MRP
(a)	(B)	(c)	(D)	(e)	(f)	(g)	(h)
1.	Ibu Gesic 500 Ml	Ibuprofen 100 mg per 5 ml	Cipla Ltd.	Pain, fever, inlammation	500 ml	25.00	60
2.	Mycobact 800	Ethambutol 800 mg tabs	Cipla Ltd.	Anti-TB, Leprosy	10 x 10	135.00	400
3.	Tetrabact-250	Tetracycline	Cipla Ltd.	Anti-biotic	10 x 10	44.00	84
4.	Cofdex P	Cough expectorant substances	Cipla Ltd.	Cough Syrup	60 ml	8.50	22
5.	Tricast – Orthopaedic Polyster Casting Tape	Casting Plaster	Samyang Corpn. – Korea Mktd By Cipla	Casting Plaster	1 pc	240.00	570
6.	Nicispas	Nimesulide 100 mg + Dicyclomine 20 mg	Cipla Ltd.	For Fever and Pain	10 x 10	35.00	250
7.	Pyzid-750	Pyrazinamide 750 mg	Cipla Ltd.	Anti TB	10 x 10	175.00	650
8.	Pregtest Kit	Pregnancy Test Kit	Cipla Ltd.	Pregnancy Test Kit	1 kit	13.00	35
9.	Coxkit-4	Combination of Anti TB drugs	Cipla Ltd.	Anti TB	15 x 2 x 1 kit	276.00	551
10.	Protibin	Vitamins and Nutrients	Cipla Ltd.	Vitamins and Nutrients	200 ml	17.50	55
11.	Gentacip- Eye Drops	Gentamycin Sulphate	Cipla Ltd.	Eye drops	600 x 5 ml	3.50	7
12.	Cafepar	Paracetamol 500 mg + Caffeine	Cipla Ltd.	For fever and pain	10 x 5 x 10	105.00	800

[17] See also Document 4, Table on Difference between wholesale price and MRP (%)

		25 mg					
13.	Doxicip-100 Cap	Doxycycline 100 mg	Cipla Ltd.	Antibiotic	20 x 10	140.00	295
14.	Fericip Tab – Chewable Tablets	Iron Polymaltose with Folic Acid	Cipla Ltd.	Irrational Iron supplement for anemia	10 x 10	170.00	450
15.	Vasotop	Nimodipine 30 mg	Cipla Ltd.	For High BP	10 x 10	250.00	600
16.	Megaclox-Lb	Ampicillin 250 mg + Cloxacillin 250 mg	Cipla Ltd.	Irrational combination of Antibiotics	10 x 10	190.00	600
17.	Nicip Md	Nimesulide 100 mg	Cipla Ltd.	For fever	10 x 5 x 10	100.00	1450
18.	Okaflox-400	Ofloxacin 400 mg	Okasa Pharma. Ltd.	Antibiotic	10 x 10	330.00	1600
19.	Suhagra-100	Sildenafil Citrate 100 mg	Okasa Pharma. Ltd	Viagra clone	10 x 4	480.00	1080
20.	Cheston-Cs Meltees	Dextromethorphan 10 mg + CPMaleate 2 mg	Okasa Pharma Ltd	Irrational anti allergic drug	10 x 10	35.00	148
21	Rofex 250 DT	Cephalexin 250 mg	Nicholas Piramal	Antibiotic	30 x 10	497.08	1879
22.	Ronimox 500 DT	Amoxycillin 500 mg	Nicholas Piramal	Antibiotic	20 x 10	362.11	1245
23	Perry-20	Omiprazole 20 mg	Indo Labs	Anti ulcer	20 x 10	104.76	800

Source of Prices: Distributor's Documents

8.11 ***Observation of Govt. Committees: ORG Retail Audit Methodology***

ORG-MARG methodology has been faulted for its gross inaccuracies and for not reflecting the field level realities of the country. We quote below from the DPCRC Report, Chapter 5:

> The ORG-MARG study on "Trends in price index of pharmaceutical formulations (1995 – 1998) conducted in March, 1999 brings out that the pharma market during the said period increased by 9.3% and the price index increased by 10.6%. It implies that there was a decline in the

quantity produced during this period which is not factually correct. While working out the index numbers for each year, the base year figures have been substantially changed by ORG – MARG for which no satisfactory reasoning is given. Clearly, a statistical bias appears to have been introduced to keep the index depressed. For instance (i) In Table 3.1.1 the value in 1994 is worked out by taking the quantity of 1995 and prices of 1994, resulting in to a lower value. And to workout the change in the price index, the value in each of the base year has been jacked up. Same is true of other tables/exercises given in the Report. Appropriately, a common base figure (1994) should have been taken to arrive at a realistic assessment of the increase in prices in 1998.

Moreover, the prices given in the ORG report are the price at which drugs are sold to the wholesale chemist. The retail prices for the consumer are those which are printed on the pack and which normally ar4 changed by the chemist after adding the local taxes etc. Therefore, the tendency of many of the manufactures to retain the price for the wholesaler static while increasing the consumer price will not reflect the real increase through the ORG study. In view of these weaknesses, the committee does (not) consider their assessment as reliable.

Likewise we have comments of the Ministry of Health (as in its comments to the DPRC) on ORG's methodology:

"*The Ministry of Health strongly feels that ORG-MARG data neither gives the real picture of the market not is it available for more than a third of the drugs falling under the essential drug list as many of such drugs are primarily used directly in the hospital based health care Cheap drugs needs to be available not only at the retail level but in the hospital care system too. Therefore, it is essential to have a database, especially in respect of all the essential drugs, to get the complete picture of their production and sale in the country. Only then would it be possible to take a more rational decision on price control. Ministry of Health supports the proposal to collect the information form the Department of Revenue in order to get the real market data about the production and sale of these drugs. This may be collected in the next one year and the list of drugs kept under price control be revised at that time. Meanwhile, the immediate exercise which will be carried out may be done on basis of data of ORG available as of March, 2001 rather than that of 1999".*

8.12 ***Inappropriateness of ORG Retail Audit for Public Health Policy***

ORG-MARG takes about 1 percent sample of the sales of the retail outlets whereas the total number of outlets is about 2.5 lacs and extrapolates sales figures therefrom. Extrapolated from a highly differentiated market where the same drug of the same

company sells at different prices in the same state, it is an extrapolation from 280 companies (roughly about 70 percent of the retail market) of a maximum of Rs 19,000 crores (ORG Retail Audit, Oct 2003, top 300 brands) of annual "retail sales". The figures themselves are not, as pointed above, retail figures: they are price to the retailer. The ORG retail audit is designed to capture the purchases made by the chemists from wholesalers. Therefore they are wholesale figures of a kind and do not reflect reality of end point sales.[18] The term "Retail Audit" is definitely misleading and a misnomer, except to say that they are a crude barometer. It also does not reflect figures of bulk institutional sales which industry estimates to be to another 30 percent, if not 50 percent of retail sales (just add defence, ESI and the drug budgets of State Governments, public sector bodies, sales to NGOs, hospitals, etc. – the predominant bulk purchasers.). It does not take into account export figures, which probably is all right considering exports do not have a direct impact on retail prices. Neither does it take into account the black-market – drugs billed that is. After all, the data collected by the Retail Audit surveyors reflects the bills of what the wholesaler decides to show. There is a considerable slice of the market, atleast about 20-30 percent, that comes under the various "schemes" of drug companies. You then also have to put in another 25 percent for spurious drugs. Spurious drugs coming in two varieties: the real drug as per label but printed and packed by some other company – so-called counterfeit drugs; the other is the case of drugs which are subtherapeutic and/or do not have the contents mentioned at all. It is also a moot point how many of the 280 companies surveyed by ORG are themselves originators of spurious drugs.

As against the frequently quoted figure of about 20,000 manufacturing units, the actual number of drug manufacturing licenses issued as of December2003 was - bulk drugs (1333), formulations (4534), large volume parenterals, (134) and vaccines (56). The total number of manufacturing units engaged in the production of bulk drugs and formulations is not more than 5877.[19] According to the Director, National Pharmaceutical Pricing Authority of the Government of India (NPPA), the number of APIs (Active Pharmaceutical Ingredients) used is 550, APIs manufactured is 400, and formulations marketed are 20,000 under 8000 brand names.[20] The NPPA monitors about 20,000 formulations.[21] . Although NPPA monitors only 8000 brands in 20,000 packs, the actual

[18] This can result in a heavily competitive environment like the segments related to antibiotic, hypertensives, etc, with the company playing with differential retail margins.

[19] Besides there are 199 medical devices units, 638 surgical dressings and 272 disinfectant units, 4645 loan licences and 318 repacking units, 1806 blood banks, 2228 cosmetics units and 287other units not covered in the above categories. [Source: Mashelkar Committee Report (2003). Figures arrived at after soliciting information from each FDA or equivalent of all states of India.]

[20] Dr Appaji, Director, NPPA, at a WHO-SEARO workshop on "Medicines in SEA Region", Chennai, Dec 22, 2003.

[21] According to NPPA's figures, 56 percent of these formulations available are based on a single ingredient bulk drug, 20 percent on 2 bulk drugs, 8 percent on 3 bulk drugs, 4

number of brands in the market would be higher. Even if we assume that on an average each of the 4534 formulators produce only 5 brands, the total number of brands would be about 20,000. Many of the big companies have over 50 brands at a time.

Accepting the above figure that there are only about 4500 formulation units, ORG audit covers only 280 companies. This would mean a significant number of regional companies are not covered. So a market size of Rs 19,000 crores is grossly underestimated. The government may carry out an exercise of comparing the ORG company turnovers with the "inland sales or retail sales" as described by companies in their profit and loss statements. This will bring out the gap between the actual turnover and ORG estimates.

Thus in a country of 2.5 lacs retail pharmacists (4 lacs according to the Mashelkar Committee Report on Spurious Drugs), to go by the retail store data of 1 % (about 2500) of retail shops, as does the ORG audit, seems to be inappropriate. Many of the drugs in our semiurban and semirural retail outlets sell drugs at extraordinarily high prices of drugs of doubtful quality at that. The irrational pricing policies affect the poor, the illiterate most.

To be fair to the ORG retail audit, it never claimed to meet these deficiencies, although they do not, understandably, mention their shortcomings. The robustness of this sampling for *policy* purposes is doubtful. As a tool for public policy making, and especially as a tool for taking care of the health and medicine interests of the poor of India, it can be even mindless to derive anything from it except to say that our pharmaceutical market is riddled with large islands of irrelevancies and irrationalities.

So what does the ORG Retail Audit figures indicate? They indicate some broad movement of the pharmaceutical market. What it says is it is monitoring what it has managed to cobble together over the years, some data that is used by drug companies to keep a tab on how the competition is doing. It is robust probably for what it does: namely to give some idea of broad movements in prices, market share of therapeutic categories – information which may be of use for producers competing for a share of the market pie. It tells manufacturers for instance what type of drugs and formulations, irrespective of the rationality of its content, will be "winners" in the market place.

8.13 ***Who Should Monitor Drug Prices?***

Given the enormous number of formulations[22], the multiple prices and the vastness of the country, the NPPA is not geared to deal with the complexity, especially to find and

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percent on 4 bulk drugs, 2.5 percent on 5 bulk drugs and 9.5 percent on 5 or more bulk drugs. Appaji as cited before.

[22] Considering that ORG audits about 280 top companies, with each company having an average of 60 brands and each brand having a line extension of at least 3 stock keeping units, this would mean, a monthly price monitoring of 280 * 60 * 3 = 50,400 packs. This is a mammoth task for any company.

monitor which product prices are zooming and which bulk drugs have reduced in prices. This probably explains the gap between the prices of controlled bulk drugs falling in the market and the fact that formulations based on the bulk drug still continue at the original levels instead of being sold at reduced rates. Let us be clear neither is the ORG-MARG apparatus geared to monitor price movements.

Drugs, low or high priced, affect the poor negatively in a country where recourse to public health systems is a dismal option. Even the so-called affordable drugs are unaffordable for most poor of the country, even for routine afflictions. The PP 2002 will only aggravate this disparity.

An important issue that has recently emerged is the question of ownership of ORG-MARG. From information available at the time of writing ORG_MARG's pharma division is sold to IMS -- an internationally known pharma market research company. (ORG-MARG's other business is now part of AC Nielsen which is owned by a Dutch Publishing Company VNU. VNU is a billion dollar Dutch media and information company with leading market positions in marketing information, media measurement and information, business information and directory publishing.). One does not have to be a conspiracy theorist, but how ethical is it for the Government of India's policy makers to rely on data collected and disbursed by a multinational with little understanding of reaching health to all the people of India? Why cannot the Government have its own data collection mechanism? The NSSO surveys have not done badly over the years.

9) Who Makes the Money in Indian Pharma Market: the Stranglehold of Retail Pharmacists

Primary bulk drug manufacturers and formulation manufacturers and do make a handsome return on their investment. We have seen above the scope of markups. In fact one of the most vested interests in the pharma market who would resist a rational pricing and drug policy tooth and nail are the retail pharmacists and their lobbies. This is because irrational drugs and tonics and syrups often enjoy 500-1000 percent trade margins. Now these margins are available even in generic drugs, which are otherwise rational. A fact acknowledged by the NPPA in its letter to IDMA appended as part of the government's petition. The situation in this regard in small towns and taluka level places and in states with relatively weak drug administration is really alarming. Drug producers are at the mercy of retail pharmacists (at last count more than 500,000 all over India). But in this the drug producers are also to be blamed. They bribe doctors as well as retail pharmacists to push sales. Retail pharmacists refuse to sell products of particular companies if margins are not increased.

> *Pharmacy owner Ranjit Ranawat smiles as he recalls how he surprised his wife one day with a new, 29-inch color television, courtesy of GlaxoSmithKline PLC's India unit.*

How did he get it? He ordered 600 vials of Fortum, an antibiotic, and 100 boxes of Ceftum, a drug for urinary-tract and respiratory infections. That's about 10 times as much as he normally would stock. Incentives to buy large quantities of prescription drugs have become commonplace in India, where thousands of drug manufacturers compete for shelf space and the country's half-million pharmacists wield an unusual amount of clout.

Pharmacists in the U.S. and other developed countries have little influence over the volume of prescription-drug sales. There, the marketing push usually targets doctors, the main legal conduit for prescription drugs. In India, many patients are too poor or too busy to see a doctor and often rely on local pharmacists for medical advice. As a result, powerful drugs are routinely, and illegally, sold over the counter....

...German Remedies Ltd., an Indian company that manufactures products under license from GlaxoSmithKline's SmithKline Beecham unit and Schering AG of Berlin, among others, recently offered a promotion dubbed "Mega Merchants: Sell and Enjoy." In exchange for buying three boxes of Primolut-N, a Schering hormone prescribed for menstrual irregularities, and several other drugs, a retailer received a free box of the antibiotic amoxycillin, and a ticket for a drawing for 124 vacations in Germany, Nepal and several Indian destinations.

Elsewhere in the same article:

'A Parallel Government'

Dilip Mehta, president of the All India Organization of Chemists and Druggists, which represents 500,000 Indian pharmacists, boasts of how his association also has forced drug companies to sign "memorandums of understanding" in which they agree to increase profit margins to pharmacies.
"They have to surrender," Mr. Mehta says, speaking from his tiny office at the rear of a wholesale apparel center in Bombay. The chemists association, he says, is like "a parallel government."

(Source: The Wall Street Journal, August 16, 2001, "Drug Firms' Incentives Fuel Abuse by Pharmacists in India" by Daniel Pearl and Steve Stecklow).

Other industry related media in India have remarked upon the tendency of pharma trade to hold the industry and consumers indirectly to ransom (see the box below 'Trade Needs to be Responsible').

TRADE NEEDS TO BE RESPONSIBLE

Wednesday, January 10, 2001 08:00 IST
P A Francis at www.pharmabiz.com[23]

The pharmaceutical trade plays a key role in making available medicines to the millions of people living in the vast expanse of this country. Without the network of five lakh odd retail stores, the drug industry just cannot sell their products. This job, therefore, is a noble and responsible function in India's healthcare management system. But, of late several members of this powerful community have not been behaving responsibly. Take the case of growing business of spurious medicines in India. It used to be an activity confined to certain streets of Delhi and UP but today is fast spreading to central and southern parts of the country. Nobody is able to control this growing menace. Who is helping these anti-social elements involved in the manufacture of spurious drugs? It is the members of the trading community. Without the co-operation of the retail trade, spurious manufacturers just cannot survive. Now, another unfair trade practice is raising its head. This time it is spearheaded by the local trade associations. Over the years, local associations have grown into powerful groups dictating terms to the pharma companies. The practice of charging a fee by trade associations from the drug companies before introduction of a new product has been there in some areas of the country. Now, it is turning out to be a highly organised practice as there is hardly any resistance from the individual drug companies.

[23] Reproduced with permission.

As reported in Pharmabiz.com, introduction of new products is increasingly becoming highly expensive in states like Maharashtra, Madhya Pradesh and Karnataka where the drug companies are required to pay Rs.500 for each product pack to district level associations. Only after obtaining a receipt of payment from the district associations, companies are allowed to introduce their products. In other states, this charge is currently levied by only the state level associations. But it is quite possible that district level associations in other states may also become demanding. In short, the companies will have to shell out Rs 4 to 5 lakh to the trade associations for a countrywide launch of just one product. No doubt, these additional costs to the pharma companies are being passed on to the consumers with no justification whatsoever. For the demanding nature of the trade associations, industry is also to be blamed as many drug companies have been pampering the trade by offering huge discounts, bonus schemes and gifts for last several years. The trade also gets huge margins for selling generic products by the pharma companies at the cost of consumer. It is not that the regulatory authorities in the country are not unaware of what is happening in the market place but most of them are ineffective or just corrupt. Some of the functioning state regulatory bodies, on the other hand, have serious resource constraints. In a situation like this, members of drug industry and trade should learn to be more responsible and accountable instead of undercutting and harming each other.

10) Circumventing Price Control: Loopholes

Having argued for reasonable price controls that do not constrict industry but one that stays focussed on the end user, one needs to pay attention to the following ways how price control has been circumvented/subverted by the industry and trade in India:

a) By ignoring price controls, ceiling prices, etc.
b) By charging officially the controlled price and taking commissions under various heads, like transportation, service charge, etc. (this is true especially for bulk drugs).
c) By bringing stay on DPCO orders
d) Making a different formulation which differs marginally: suppose aspirin 300 mg is under price control sold in blister packs of 10s. Then if one makes aspirin 300 mg plus Vitamin C 1 mg or aspirin plus Calcium Carbonate, one can be out of price control. Or one can make a different pack size and/or a different packing.
e) By having different presentations: say the price control was levied on Aspirin 75 mg coated tablet. Then you make Aspirin enteric coated and get out of the price control till NPPA gets wise to the situation.
f) By declaring the product to be Ayurvedic. You can avoid price control and in some cases even get excise exemption. Vicks Vaporub and Eno's Fruit salt are now Ayurvedic products.
g) By making it in a different smaller company on contract and the main company just markets it. You can avoid excise or get excise reductions up to certain limits. Many a time the smaller company often exists on paper. It can be a loan licensee of the bigger company.

h) "Price regulation, a mockery": Sometimes formulation companies are beneficiaries of India's vast pharma industry and/or the tardiness of regulatory authorities. The bulk price would have fallen drastically but the DPCO controlled formulation price is based on the higher price. In the phase lag between price reductions in bulk drug and the date the new reduced ceiling price of formulations are announced, the drug company stands benefitted.

> Take the case of ciprofloxacin, a drug under price control. Its current market price is just around Rs 1,450 per kg. Against this, manufacturers are getting formulation prices fixed at the rate of Rs 4,190 per kg from NPPA. The price was last revised in March, 1997. There are at least a dozen other drugs for which the market prices are much below their notified prices. Another highly unethical trend in this industry is in the area of generic marketing. Many large companies have now introduced generic products for most of their branded products. And the margins the companies are offering to the trade for these products are 500 to more than 1000 per cent on a strip. In other words, the prices at which the manufacturers are printing on the packs of generics are almost comparable to the branded products but their selling price to the trade may not be even 10 percent of the MRP. In short, the benefit of lower prices of bulk drugs is denied to the ultimate consumer on account of the greed of the manufacturers and due to the inefficiency of the NPPA. It is high time the regulatory authorities across the country intervened and brought an end to these unethical practices in this industry. ("Price regulation, a mockery", *Pharmabiz.com editorial, June 20, 2000*[24]*.)*

11) Concluding Remarks

In this paper we have tried to show that price control policy in PP 2002 tries to ignore and bypass the real issues of high margins, multiple pricing of essential drug formulations, and how drugs that are necessary for the disease pattern of the country are out of price control. Competition does not work uniformly in the pharma industry. Nor in health services catered to by private sector. So taking drugs mindlessly out of price control in the name of liberalisation and softening the rigors of price control is in reality pandering to an industry driven agenda. There is a stranglehold in the market also of the retail pharmacists who appear to be a law unto themselves.

The criteria in PP 2002 for drugs to be in the price control basket, or out of it, is highly flawed as also its reliance on the figures of the ORG-AC Nielsen's so-called retail audit sales. These in themselves are not relevant data for public health policy making, and not even for pharmaceutical price policy making. . The PP 2002 criteria will end up driving down the basket of price control to some 30 odd drugs.

Price control of medicines is the norm even in developed countries. The eagerness of the Government of India – ignoring the observations of its own Parliamentary Committee Report and that of the Government appointed Drug Price Control Review Committee-- is a profound piece of unreason and folly. It is not only missing the woods for the trees. But

[24] Reproduced with Permission.

it is asking the people of India to look at the cake and pastry industry, and eat the cakes too if you can afford it, when the majority continue to be driven to despair because they cannot afford medicines as much as a single decent meal in a day.

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CHAPTER 2

ANARCHY IN RETAIL DRUG PRICES IN INDIA[1]

- Anurag Bhargava, Smita Khobragade and Meenakshi Jambulkar

Govt to crack down on drug price abuse

BS Regional Bureau in Ahmedabad | August 06, 2004 09:15 IST

Source: http://inhome.rediff.com/money/2004/aug/06drug.htm

Union Minister for Fertlisers and Chemicals Ramvilas Paswan said that the central government has resolved to check the practice of drug overpricing.

Also, action will be taken against both producers and wholesale distributors of medicines in a bid to check the malpractice.

Paswan, addressing a function in Ahmedabad on Thursday, said the government has also formed a committee headed by a joint secretary in the fertlisers and chemicals department with members from the law and health ministries.

The committee will make a revised list of drugs that are classified under the essential and life saving drugs list.

"The government intends to control the prices of at least essential drugs and life saving drugs. Data available for the period between 1994 and 2004 have shown that while drug prices, which are controlled by the government, have risen by 0.75 per cent annually, prices of drugs which are not under government control have risen by 10.6 per cent yearly," the minister said.

Referring to a report that his ministry had sought from the National Pharma Pricing Authority, Paswan said patients and their relatives were being 'looted' by companies.

"There are four stages here. The first is the cost of production for the manufacturer, the second the rate at which the wholesaler is being given medicines, the third is the rate at which chemists or retailers are receiving medicines, and the fourth is the rate at which people are buying.

"Even if a 100 per cent extra charge is levied at each stage, the price of the medicine must not increase more than four-five times of the production cost. We have found out that it is 30 times more in some cases," the minister said.

He said according to the law nobody can charge more than 100 per cent or double than the rate at which he has received a medicine….

…A study on trade margins of select medicines by the NPPA has shown that the price of a drug increases by around 30 times by the time it reaches the consumers.

For example, the purchase price of the retailer for a 10-tablet strip cetrizine 10 mg ranges between one rupee and two rupees (13 producers of cetrizine have been considered), while the printed price ranges from Rs 22 to Rs 36.

[1] This is a revised and updated version of 'Tremendous Variations In Drug Prices In The Indian Pharmaceuticals Market' by Anurag Bhargava, in the earlier edition (Jan 2004).

Similarly, for a 10-tablet strip of nimesulide 100 mg, the purchase price for the retailer ranges between Rs 1.20 and Rs 2, while the printed price ranges between Rs 22 and Rs 29, as 11 pharmaceutical companies were considered.

Commenting on the need to bring more medicines under the essential list, Paswan said at least prices of life saving drugs need to be controlled by the government.

Introduction

Healthcare, and drug expenses at that, is the surest route to impoverishment in India. And we are glad at last a Union Minister has called a spade a spade.

The Reserve bank of India (RBI) Rural Indebtedness survey of late eighties showed that amongst non-production loans healthcare was the first reason and amongst all loans it was the second reason for indebtedness. Similar conclusions have emerged from the 52nd round of the NSSO.[2]

A World Bank document using the same NSSO data concludes:[3]

- More than 40 percent of those hospitalized borrow money or sell assets to meet expenses
- At least one quarter of hospitalized Indians fall below poverty line because of hospitalization and related costs.
- Only 10 percent of Indians have some form of insurance which itself is not adequate.
- Out of the total annual expenditure on healthcare by Indians, hospitalization costs account for more than half (58%).

This is a direct reflection of other realities of continuing levels of poor investment in heath in India by the government with resultant out-of pocket expenditures which are among the highest in the world (people meet 83% of the total expenditure, with government spending only 17%), of rising costs of health care, a substantial part of which goes towards purchase of drugs. In India drug costs constitute around 40-50% of the costs of treatment.[4]

Progressive deregulation of drug prices in the 1990s has been responsible for the worsening situation with regard to drug costs. And this has a tremendous impact on people because a substantial part of the expenditure even for the poor is in the private sector.[5] "A recent NCAER study reveals that the richest 20% enjoy three times the share of public subsidy for health compared with the poorest quintile. The poorest 20% of Indians have more than double the mortality rates, fertility rates and undernutrition levels of the richest 20%. The poor suffer disproportionately more from pre-transition diseases such as malaria and TB. On

[2] Sen Gita, Iyer Aditi, George Asha, "Structural Reforms and Health Equity, A Comparison of NSS Surveys, 1986-87 and 1995-96," *Economic and Political Weekly*, April 6, 2002, p. 1342-1352

[3] David.H.Peters, Abdo.S.Yazbeck, Rashmi R. Sharma, G.N.V. Ramana, Lant H. Pritchett, Adam Wagstaff. *Better Health System For India's Poor: Findings Analysis and Options.* The World Bank, 2002, Washington. See also *Rising the Sights: Better Health System for India's Poor, Overview.* The World Bank, Washington (DC): 2001, p.2

[4] op.cit NSSO 52nd Round and references 1 and 2 as cited above.

[5] Gita Sen, et al, op.cit.

an average, they spend 12% of their incomes on healthcare, as opposed to only 2% spent by the rich. Treatment or hospitalization for chronic illness often means the liquidation of meagre assets, even permanent indebtedness. One episode of hospitalization is enough to wipe out all the assets of the family. It is no wonder then that the number of the poor who did not seek treatment because of financial reasons increased from 15% to 24% in rural areas and doubled from 10% to 21% in urban areas in thedecade 1986-96."[6]

The irony of this situation is that despite the misery inflicted by rising health care costs, and the decline of governmental spending on health, the previous NDA government with its Pharmaceutical Policy 2002 is paving the way for further increases of drug prices by virtually doing away with the mechanism of price regulation for essential drugs.

Survey of Variation in Retail Prices of Branded Drugs

If one surveys the prices of branded drugs in the market one is struck by the marked variation in prices between different brands. This variation is true for any drug, whether a new product or an established product.

In this article we first offer the results of a survey of retail prices of drugs belonging to different categories, and listed in the well-known Indian prescriber's handbook, *Current Index of Medical Specialties* (CIMS®), in its issue of April 2004. Along with the retail prices of the most expensive and the least expensive brand, we have also provided two other pieces of information:

- One is whether the drug is listed under the price control order (DPCO) 1995 (and whose retail price is therefore under control).
- The other is whether the drug is mentioned in the National List of Essential Medicines 2003. This list is supposed to contain the drugs required for the priority healthcare needs of India; and therefore have been carefully selected with regard to their public health relevance, safety, efficacy and cost-effectiveness by a committee of experts.

Drugs under price control should have little variation in their price and that the drugs in the National List of Essential Medicines should by virtue of their importance to public health and their cost-effectiveness should be available at affordable rates to the people.

The collation of the price information along with these two pieces of information allows us also to arrive at an understanding of some of the anomalies of the state of drug pricing and its control in India:

[6] Quoted in *Changing the Indian Health System: Current Issues,Future Directions,* ICRIER, New Delhi at http://www.icrier.res.in/pdf/RajivMishra3.pdf

- There are many drugs -- for instance many antibiotics, most antihypertensives, and all anti-cancer drugs – that should have been under price control because they are essential medicines.

- On the other hand, there are some drugs which are not listed in the National List of Essential Medicines (NEML 2003), and neither under price control but which are highly priced and as we shall see in the chapter on "Anomalies of Drug Pricing and Sale of Drugs in India" and which have turnovers in crores.

As shown in the tables variations of 200% or more are quite common in the market. For example, for a drug like Inj. Ceftriaxone, the brand made by E- Merck costs Rs. 50 per 1 gram, while the same drug made by JK Industries, costs Rs 211.3 per 1 gram. Or a drug like Azithromycin made by one well-known company can sell at Rs. 8.50 per tab. while another company can sell the same drug at Rs. 37 per tablet.

For at least 26 drugs we have documented price variations of more than 400% between 2 brands of the same drug , an astronomical variation. The variation moreover is not between a large company and a smaller one. In most instances the company marketing the drug at the least price is also a well known company. Therefore these marked variations can only be interpreted as overpricing without any logic except the opportunity to increase the profits on a log scale.

Table 1: Drugs with Astounding (> 400 %) Variations in Prices between Brands[7]

(Price in Rupees)

No	Drug	Use	Under price control?	In National List of ess-ential medicines?	Retail price per tablet of lowest priced brand/ manufacturer)	Retail price per tablet of highest priced brand/manu-facturer	Highest priced/ lowest priced x 100
1.	Fluconazole 150 mg	Anti-fungal	No	Yes	1.50 Flusyst / Reliance	32.00 Syscan / Torrent	
2.	Rabeprazole 20 mg	Antiulcer	No	No	0.45	9.25	2055%
					Rabera / Jenburkt	Happi / German remedies	
3.	Famotidine 20 mg	Antiulcer	Yes	Yes	0.24	3.75	1562%
					Famtac / Nicholas Piramal	Autidine / Aurobindo	
4.	Cycloserine 250 mg		No	Yes	4.50	67.00	1488%

[7] Source of Price Data: CIMS® *(Current Index Of Medical Specialties*), April 2004
Local Taxes Extra

	Anti-TB drug (second line)				Myser / Panacea	Cyserine / VHB	
5.	Domperidone	Anti-vomiting drug	No	Yes	0.25	3.29	1316%
					Vomistop / Cipla	Gastractiv / Ethnor	
6.	Ofloxacin 200 mg	Antibiotic	No	Yes	2.90	31.00	1068%
					Zo / FDC	Tarivid / Aventis	
7.	Amlodipine 5 mg	Anti-Hypertensive	No	Yes	0.50	4.81	962 %
					Amlodac/ Alidac	Amlogard / Pfizer	
8.	Flutamide 250 mg	Anti-cancer drug	No	Yes	9.00	73.66	818%
					Flutide / Samarth	Drogenil/ Fulford	
9.	Busulphan 2 mg	Anti-cancer drug	No	Yes	0.69	5.40	782%
					Busuphan / Elder	Myran / VHB	
10.	Ondansetron	Anti-vomiting agent	No	Yes	2.50	19.20	768%
					Anset / Depone	Zondan / GSK	
11.	Omeprazole 20 mg	Anti-ulcer	No	Yes	0.58	4.32	744%
					Omecip / Cipa	Omez / Dr. Reddy's	
12.	Sparfloxacin 200mg	Antibiotic	No	No	4.04	29.16	721%
					Sparcip / Cipla	pardac / Alidac	
13.	Cefuroxime axetil 350 mg	Antibiotic	No	No	Yes 5.40	7.50	694%
					Comed / Milicef	Ceftum captabs / GSK	
14.	Inj. Dobutamine 1amp	Heart failure, shock	No	Yes	58.00	400.00	689%
					Panacea	Troikaa	
15.	Atenolol 50 mg	Anti-hypertensive	No	Yes	0.40	0.30	575%
					Zybloc/ FDC	Tenormin/ icholas ramal.(185)	
16.	Phenytoin 100 mg	Anti-epileptic	No	Yes	0.21	1.19	566%
					Epileptin / IDPL	Dilantin/ Parke- Davis	

17.	Pioglitazone 15 mg	Anti- diabetes	No	No	0.90	5.00	555%
					Pio-15 / Systopic	Piozone / Nicholas Piramal	
18.	5-Fluorouracil	Anti-cancer	No	Yes	21.00	112.00	533%
					Flucil / Samarth	Fluracil / Biochem	
19.	Paracetamol 500 mg	Anti-pyretic	No	Yes	0.15	0.75	500%
					Paracip	Calpol	
20.	Rofecoxib 25 mg		No	No	0.80	4.00	500%
		Anal- gesic, anti- Inflammatory					
21.	Glimepride 2 mg	Anti-diabetes	No	No	2.18	10.34	474%
	Anti-diabetes				Gepride / Medley	Amaryl / Aventis	
22.	Azithromycin 250 mg	Antibiotic	No	Yes	8.50	39.14	460%
					Zathrin / FDC	Vicon / Pfizer	
23.	Ceftriaxone 1 gm	Antibiotic	No	Yes	50.00	211.30	423%
					Gutencef / Emerck	INOCEF / JK Ind.	
24.	Gliclazide 80 mg	Anti-diabetes	No	No	1.40	5.88	420%
					Gliclaz / Khandelwal	Diamicron / Serdia	
25.	Losartan potassium 50 mg	Anti- hypertensive	No	Yes	1.70	7.00	411%
					Zylos/ FDC	Repace / Sun	
26.	Doxycycline 100 mg cap	Antibiotic	Yes	Yes	1.55	6.20	400%
					Codox / Comed	Doxypal / DR, Jagsonpal	

Many of these drugs like Omez, Ceftum, Tenormin, Amaryl, Diamicron, Calpol, Dilantin, are the costliest and overpriced by a huge margin. However that does not stand in the way of the costliest selling far more than their competitive brands that may be 400% cheaper.

This situation is quite surprising for a market that is supposedly regulated and monitored by the Government of India through its drug price control order and by an autonomous authority called National Pharmaceutical Pricing Authority.

Variations in Prices of Drugs under 'Price Control' - And What it Means

The DPCO 1995 basing itself on some market share and turnover based criteria considered 74 drugs (out of the total of around 550 active pharmaceutical drugs) to be of mass consumption and in which there was presence of insufficient competition. These were placed under price control. The implementation of this order and monitoring the industry's compliance with it is the responsibility of the National Pharmaceutical Pricing Authority and State Drugs Controllers. The violation of the price control order is a cognizable offense.

In light of the above it would be expected that there would be no significant variation between the ceiling price as recommended by the NPPA and the retail price at which they are available in the market. But we show below that is not the case.

Myth and Reality of Price Control

The ceiling prices as recommended by the NPPA (exclusive of excise duties and local taxes) and the retail price of the highest priced brand (exclusive of the local taxes) as mentioned in the regularly updated popular prescriber handbook CIMS (Current Index of Medical Specialities) issue of April 2004 were compared. These are presented in Table 2. In many instances the rates were confirmed from the retail market.

- *Contrary to expectations, in 34 instances out of 74 drugs we observed significant price violations. Thus in around 46% of the total number of drugs under the DPCO, there was found to be violations of drug price control order.*

- *The variation between the ceiling price (with the addition of excise duty) and the retail price of the highest priced drugs was a minimum of around 150% and upto maximum of 400-500% in the case of aspirin and captopril.*

- *Antibiotics form a large part of the drugs found violating the drug price control order. Antibiotics are the major therapeutic group in terms of sales in India,contributing to 17.6% of the total sales of over 20,000 crores of the pharmaceutical industry in India..* There are 19 anti-infectives in the list of 34 drugs violating the DPCO. These include commonly used antibiotics like ciprofloxacin, norfloxacin, cefadroxyl,doxycycline, cloxacillin combinations with ampicillin, rifampicin, etc. The total extra earnings for the pharma companies and thereby loss for the consumer, with the price violations in this segment alone would amount to hundreds of crores,

- Price control violations were seen in other categories characterized by high volume sales, like the anti-inflammatory group (aspirin, ibuprofen), anti-diabetics (glipizide), anti-hypertensives(captopril, methyldopa), CNS drugs (carbamazepine).

- Because of these violations there are now virtually no drugs under some categories which can be considered as under price control.

    i. Anti-hypertensives: Both captopril and methyldopa which were the only drugs for hypertension have price violations.
    ii. Analgesics: With the price violations in aspirin, ibuprofen, and dextropropoxyphene, what are left are analgin (which is banned in most countries including Sri Lanka, Nepal, and should not be available in India in the first place) and pentazocine(drug has to be given parenterally).
    iii. Anti-ulcer drugs: Both ranitidine and famotidine which are the only such drugs under price control have price control violation.
    iv. Oral hypoglycemics: Glipizide has price violation as noted. The only other drug is chlorpropamide that has fallen out of favor because of its greater propensity for causing prolonged hypoglycemia.

- Although in the tables the highest priced brand is mentioned as the violator of price control, numerous other popular brands have been noted to be violating the ceiling price, making the phenomenon of price violation widespread.The violators of price control are not some small low profile manufacturers violating the rules secretly but more often large scale manufacturers violating the rules openly.

- *For example:* Doxycyline, other brands like Doxy-1 (USV), Biodoxi(Biochem), DoxtDr. Reddy's were all found to be violating price control prices.
  The companies violating the DPCO include the likes of Cadila, Cipla, Dr. Reddy's, Wockhardt, Glaxo Smith Kline etc.

- The contents of the DPCO 1995 were themselves anomalous from the public health point of view because they excluded many essential drugs. The violations of the DPCO 1995 in the area of the most commonly used drugs have made it an order irrelevant and lifeless for the people.

Implications

a. *Impairing access to treatment and wastage of poor people's precious resources:* As mentioned many poor people do not access health care because of the costs involved, and many undergo loss of assets, and indebtedness as a result of health care costs. The annual transfer of hundreds of crores, courtesy these price violations, to pharma companies from the pockets of poor patients is unwarranted, illegal.

b. How were such violations allowed to be perpetrated?

This state of affairs shows the regulatory bodies of the government, in a poor light. The inability of the regulatory bodies like the NPPA to monitor and regulate the prices of just 74 drugs is a blow to its authority and credibility. While reducing the basket of price-controlled drugs the government has always said that close watch would be kept on the drugs going out of price control. If it cannot watch the prices of

a mere 74 drugs that are under price control, to talk of monitoring and regulating prices of drugs that are now out of price control is hardly plausible.

It appears as if the writ of the NPPA does not run on the pharmaceutical manufacturers.

c. We are well aware of the lax drug regulatory system in India, in the field of approval of new drugs. Pharmaceutical companies complain bitterly about price regulation, and have always lobbied for a control free market. *To talk of the rigors of price control on the one hand and to overcharge the patients on the other hand denotes plain double-speak.*

d. Price control has been an important tool of India's public health policy to increase access of the poor to essential medicines. Prices were fixed in a way to ensure reasonable profits for the pharmaceutical industry and trade. *However progressively the pharmaceutical policy in India has moved away from this balancing of the interests of the consumers and the industry to assume a clearly pro-industry slant.*

> Government will keep a close watch on the prices of medicines, which are taken out of price control. In case the prices of these medicines rise unreasonably, the Government would take appropriate measures, including reclamping of price control.
>
> *-Excerpts from the Modification of Drug Policy 1986, in 1994*

Each time the people have been reassured not to be alarmed about the relaxation of price controls, since the Government would be monitoring the prices of drugs and safeguarding the public interest by reclamping price control.

> However, keeping in view the interest of the weaker sections of the society, it is proposed that the Government will retain the power to intervene comprehensively in cases where prices behave abnormally."
>
> *-Excerpt from the Pharmaceutical Policy 2002*

An authority called the National Pharmaceutical Pricing Authority was created in 1997 to monitor compliance with the provisions of the Drug Price Control Order, to monitor drug prices even in decontrolled category and to fix prices periodically of bulk drugs and formulations. This agency has taken action in some cases of violation of the drug price control order, and also in some drugs outside price control like I.V. fluids that had a good impact on their prices.

The marked variation in the prices of price-controlled drugs and the apparent lack of action by the Government agencies is hardly in keeping with the promises and reassurances that the people have been given on regulation of drug prices.

Table 2: List of Drugs under DPCO, 1995
Which have Violations of the Price Control Order[8]

No.	Drug	Use	NPPA ceiling price (exclusive of excise duty and local taxes)	Highest price brand available in the market (exclusive of local taxes) along with manufacturer
1.	Aspirin 325 mg	Analgesic, Antiplatelet	Rs.0.20	Rs. 1.48 Manospirin/ Mano
2.	Captopril 25 mg	Hypertension , heart failure	Rs.0.84 per tab	Rs.3.9, Aceten Wockhardt/Tridoss
3.	Carbamazepine Syrup 100 ml, 100 mg/5ml	Epilepsy	Rs.21.24	Rs.40.07 Mazetol/SPPL
4.	Rifampicin 450 mg	Antibiotic in TB	Rs. 4.74	Rs.8.09. Macox (Macleods), also Zucox (GSK) Rs. 6.89
5.	Cefadroxyl 500 mg	Antibiotic	Rs. 6.50	Rs.13.32 Kefloxin, Solus
6.	Cefotaxime 1g	Antibiotic	Rs. 29.68	Rs.110.00 Oritaxim, Alidac & others.
7.	Ciprofloxacin 500 mg	Antibiotic	Rs. 5.97	Rs.8.96 Cifran, Ranbaxy
8.	Ampicillin 250 mg + Cloxacillin 250 mg cap Inj. Ampicillin and cloxacillin 250 mg+250 mg	Antibiotic	Rs. 2.67 Rs. 7.02 per vial	Rs. 7.31, Roscilox, Stancare, numerous other violators Rs. 26.09 per vial,Biclopen/P&B Rs. 24.0 Megaclox/Cipla and others
9.	Cloxacillin 500 mg	Antibiotic	Rs.2.38	Rs. 4.0 Clocilin, PCI
10.	Chloroquine 250mg	Antimalarial	Rs.0.57	Rs.0.93 Emquin E-merck
11.	Chlorpromazine 50 mg	Antipsychotic	Rs.0.52	Rs.0.90 Sunpharma
12.	Cefazolin 1 g	Antibiotic	Rs.31.78	Rs.65.30. Azolin,
13.	Doxycycline 100 mg	Antibiotic	Rs.0.98	Rs.6.2 Doxypal-DR, Jagsonpal
14.	Erythromycin 250 mg	Antibiotic	Rs.2.17	Rs. 4.32 Elucin, Ind-Swift
15.	Famotidine 20 mg	Anti-ulcer	Rs.0.21	Rs. 3.75 Autidine, Aurobindo

8 Source of Ceiling price data: NPPA list of ceiling prices of scheduled formulations (as on July 1, 2004) Source of retail price data: CIMS April 2004

No.	Drug	Use	NPPA ceiling price (exclusive of excise duty and local taxes)	Highest price brand available in the market (exclusive of local taxes) along with manufacturer
16.	Ibuprofen 400 mg	Analgesic	Rs.0.46	Rs.0.91 Ibrumac , Macleods
17.	Nalidixic acid 500 mg	Antibiotic	Rs1.88	Rs. 5.50 Dix, PCI
18.	Norfloxacin 400 mg	Antibiotic	Rs.1.87	Rs. 4.7 Norflox, Cipla
19.	Salbutamol 4 mg	Asthma medication	Rs.0.14	Rs.0.78 Salbu, P&U
20.	Methyldopa 250 mg	Hypertension	Rs.2.36	Rs.3.40 Emdopa, IDPL
21.	Prednisolone 10 mg	Steroid for use in multiple condtions	Rs.0.76	Rs. 1.47 Wysolone, Wyeth
24.	Ranitidine 150 mg	Anti-ulcer	Rs.0.46	Rs.1.06 Aciloc, Cadila, Ridcer, Gufic
25.	Glipizide 5 mg	Diabetes	Rs. 0.43	Rs. 1.10 D-Glip, Grandix
26.	Pentoxifylline 400 mg	Peripheral vascular disease	Rs. 2.36	Rs. 5.81, Flowpent, Knoll Pharma
27.	Tetracycline 250 mg	Antibiotic	Rs. 0.72	Rs.1.57 Tetracycline, Dabur
28.	Lincomycin inj. 300 mg/ml	Antibiotic	Rs. 16.22	Rs. 34.00, Lincocin, Max
29.	Sulphamethoxazole-Trimethoprim 800 mg +160 mg respectively	Antibiotic	Rs. 0.96	Rs. 1.59, Cotran DS Bengal immunity
30.	Pyrantel pamoate	Anti-worm	Rs. 2.20	Rs.4.7 Expent Merind.
31.	Tolnaftate 15 ml Lotion 10 mg/ml Cream 10 mg/g 10 g.	Antifungal	Rs. 8.86 Rs. 5.30	Rs. 20.0 Tinaderm, Fulford Rs. 20.05 Tinaderm, Fulford
32.	Griseofulvin 250 mg	Antifungal	Rs.1.60	Rs. 2.2 Walavin-250, Wallace for 250 mg
33.	Sulfadoxine+ pyrimethamine 500 mg + 25 mg	Antimalarial	Rs.2.82 for 2 tablets	Rs. 4.74 for Rimodar Anglo-French and others.
34.	Dextropropoxyphene + Paracetamol : 65 mg + 325 mg.	Analgesic	Rs. 0.62	Rs. 1.47 for Parvon which contains 65 mg dextropropoxyphene with 400 mg paracetamol

Variations in Prices of Decontrolled drugs

We now present our findings on the variations in retail prices of those drugs, which are not listed in the DPCO 1995, and are therefore outside price control. As noted earlier the number of such price-decontrolled drugs is constantly on the rise both with the introduction of newer drugs in the Indian market and with the decrease in the number of drugs in the price control basket.Many of these drugs which are outside price control are in fact essential medicines and the variation in their prices is a serious issue impairing poor people's access to drugs. This is the case with many antibiotics including drugs for TB, resistant malaria, diarrhea, drugs for hypertension, drugs for cancer.

Table 3: Variation in Prices of Decontrolled Drugs

Sl. No.	Name of Drugs	Under price control	In National list of essential medicines	Lowest Price In Rupees, Brand, Manufacturer	Highest Price In Rupees, Brand, Manufacturer	Ratio of highest/lowest expressed as a percentage. Highest/lowest x 100
Drugs for Infections with Worms						
1	Mebendazole			0.85	2.3	270%
		No	yes	Idibend, IDPL	Mebex, CIPLA	
2.	Albendazole			5.99	12.75	212%
	400mg1 tab	No	Yes	Bandy, Mankind	Noworm Alkem	
3.	Diethyl carbamazine citrate.			0.24	0.43	179%
	100mg tab	No	Yes	Banocide, GSK	Hetrazan, Wyeth-lederle	
Drugs for bacterial infections: like pneumonia, urinary tract infections						
4	Ofloxacin 200 mg	NO	Yes	2.9	31.0	1068%
				Zo, FDC	Tarivid, Aventis	
5.	Sparfloxacin 200 mg	No	NO	4.04	29.16	721%
				Sparcip, Cipla	Spardac, Alidac	
6.	Cefuroxime axetil	No	Yes	5.4	37.5	694%
	250 mg1 tab			Milcef, Comed	Ceftum captabs,GSK	
7.	Azithromycin	No	Yes	16.5	78.3	460%
	500mg 1 tab			Zathrin, FDC	Vicon,Pfizer	
8.	Ceftriaxone	No	Yes	50	211.3	422%
	1 gm			Gutencef Emerck	Inocef JK ind	
9.	Doxycycline	Yes	Yes	1.55	6.2	400%
	100mg1 cap			Codox, Comed	Doxypal DR,	

					Jagsonpal	
10.	Cefixime 100 mg	No	No	7.75	27.0	348%
				Zifi , FDC	Cifix, Cipla	
11.	Cefadroxil *	Yes	No	4.02	13.32	331%
	500 mg 1 tab			Ococef, Ochoa	Kefloxin,Solus	
12.	Cefotaxime1 gm	Yes	Yes	33.54	110	327%
				Omnatax,Ni cholas piramal	Oritaxim, Alidac	
13.	Ciprofloxacin	Yes	yes	2.9	8.53	294%
	500mg1 tab			Zoxan, FDC	Cifran, Ranbaxy	
14.	Roxithromycin 150 mg	No	Yes	4.5,		
				Roxibest , Blue Cross	Rulide, Aventis	
15.	Ciprofloxacin*	Yes	Yes	15.92	39.95	250%
	200mg/100ml1 vial			Alcipro Alkem	Strox, Dabur	
16.	Amoxicillin	No	Yes	3.09	7.75	250%
	500 mg1 tab			Hipen, Zydus Cadila	Maxmox, Max	
17.	Clarithromycin	No	yes	30	68.75	229%
	500 mg 1 tab			Clariwin, Brown and Burk	Clarimac, Cadila health care	
18.	Inj.Amikacin 500 mg vial	No	Yes	30.0	66.0	220%
				Amicom, Comed	Sanmica, Sanjivani	
19.	Inj Ampicillin	No	Yes	9.63	18.50	199%
				Albercilin, Aventis	Broadicilin, Alkem	
20.	Cephalexin	No	yes	6.8	12.09	177%
	500 mg1 tab			Cephacure, Orchid	Oriphex, Alidac	
21.	Cloxacillin*	Yes	yes	2.6	4..0	162%
	500 mg1 tab			Bioclox, Bo	Clociliin PCI	
22.	Erythromycin	Yes	Yes	2.64	4.32	160%
	250mg 1 tab			Erolcid, Pharmacia	Elucin, Ind-Swift	
23.	Ceftazidime 1 g	No	Yes	250	334.17v	133%
				Superzid ,	Fortum, GSK	
24.	Gentamycin	Yes	Yes	6.96	8.35	120 %
	40mg/ml,1 vial			Tamiacin, Sun Pharma	Refragen, Sythiko	
Some Drugs Used in Treatment of Tuberculosis Including Drug Resistant TB						
25.	Cycloserine	No	No	4.5	67.0	1488%
	250mg, 1 tab			Myser,Panacea	Cyserine VHB	
26.	Ethambutol	No	Yes	1.28	4.16	325%
	800 mg I tab			Tibitol, PCI	Mycostat, Overseas	
27.	Rifampicin	Yes	Yes	3.25	8.09	249%

	450 mg, I tab			Rifacilin, PCI	Macox, Macleods	
28.	Pyrazinamide	No	Yes	2.6	6.5	250%
	750 mg,1tab			Rizap, GSK	P-Zide,Cadila	
29.	Ethionamide	No	No	9.9	16.6	167%
	250 mg,1 tab			Tumid, Samarth	Etumid, VHB	
DRUGS USED IN FUNGAL INFECTIONS:						
30.	Fluconazole	No	Yes	1.58	32.0	2133%
	150 mg1 tab			Flusyst, Reliance	Syscan,Torrent	
31.	Amphotericin B	No	Yes	221.17	457.0	206%
	50 mg vial1 VIAL			Fungizone,SPPL	Mycol, VHB	
Drugs Used in Viral Infections Including HIV/AIDS						
32.	Zidovudine	No	Yes	8.00	53.52	669%
	100 mg1tab			Zido-H, Genix	Retrovir, Burroughs-Welcome	
33.	Lamivudine + Zidovudine	No	Yes	27.4	82.0	299%
	150 mg + 300 mg1 tab			Duovir, Cipla	Combivir, GSK	
Drugs Used in Heart Disease, Hypertension, High Cholesterol						
34.	Amlodipine	No	Yes	0.5	4.81	962%
	5 mg1tab			Amlodac, Alidac	Amlogard, Pfizer	
35.	Atenolol	No	Yes	0.4	2.3	575%
	50mg1tab			Zybloc, FDC	Tenormin, Nicholas Piramal.(185)	
36.	Inj. Dobutamine			58.0	400	689%
	1 amp			Panacea	Troikaa	
37.	Atorvastatin 10 mg	No	Yes,	2.4	11.86	494%
				Zivast, FDC	Atorva,Zydus cadila (160)	
38.	Losartan potassium 50 mg	No	Yes	1.7	7.0	411%
				Zylos, FDC	Repace, Sun	
39.	Isosorbide-5-mononitrate	No	Yes	0.77	2.75	357%
				Isomin-20, Cipla	Angicor,Sandoz	
40.	Propranolol	No	yes	0.56	1.8	321%
	40 mg1tab			Medley	Mano	
41	Diltazem 30mg 1tab	No	yes	0.99	2.38	255%
41.	Diltazem 30mg 1tab	No	yes	0.99	2.38	255%

				Diltime,Cadila health care	Ionozem Parke davis	
42.	Enalapril 5 mg	No	Yes	1.20	2.80	233%
				Enpril,Wockardt	Dilvas, Cipla	
43.	Lisinopril 5 mg	No	No	2.5	5.97	238%
				Lisopril, Themis	Zestril, Astrazeneca	
Drug Used in Heart Attacks						
44.	Inj.Streptokinase Streptokinase1.5 million units1 vial	No	Yes	1900.0	3898.09	205%
				Dabur	Indon	
Drugs Used in Diabetes						
45.	Pioglitazone	No	No	0.9	5.0	555%
	15 mg1 tab			Pio-15, Systopic	Piozone, Nicholas	
46.	Glimepride	No	No	2.18	10.34	474%
	2mg1 tab			Gepride, Medley	Amaryl, Aventis	
47.	Gliclazide	No	No	1.4	5.88	420%
	80 mg1 tab			Gliclaz, Khandelwal	Diamicron, Serdia	
48.	Glipizide	Yes	No	0.63	1.51	239%
	5 mg1 tab			M-Diab, Dominion	G-Trol, Mano	
Drugs Used in Cancer						
49.	Tamoxifen	No	Yes	1.55	19.03	1227%
	10 mg 1 tab			Oncomox, TDPL	Nolvadex, ICI	
50.	Flutamide 250 mg	No	Yes	9.0 Flutide, Samarth	73.66 Drogenil, Fulford	818%
51.	Busulphan	No	Yes	0.69	5.4	782%
	2 mg1			Busuphan, Elder	Myran, VHB	
52.	5-Fluorouracil	No	Yes	21 Flucil, Samarth	112 Fluracil, Biochem	533%
53.	Paclitaxel 30 mg	No	Yes	1805 Neotaxl VHB	5000 Intaxel, DAbur	277%
54.	Bleomycin	No	Yes	840.16	1300	155%
	15 units1 vial			Bleochem, Biochem	Bleonco,VHB	
55.	Doxorubicin	No	Yes	895	1302.0	145%
	50 mg,l1 vial			Adosal, VHB	Doxorubicin, Khandelwal	
Drugs for Pain, Fever, Inflammation						

56.	Paracetamol	No	Yes	0.15	0.75	500%
	500 mg			Paracip	Calpol (45)	
57.	Rofecoxib 25 mg	No	No	0.80	4.0	500%
				Cyclorof/FDC	Roff/ Unichem	
58.	Nimesulide 100 mg	No	No	0.82	2.90	353%
				Nimica/Ipca	Nimulid/Panacea (107)	
59.	Diclofenac	No	Yes	0.60	1.20	200%
				Diclofam/Max	Diclonac/Lupin	
60.	Serratiopeptidase	No	No	2.90	5.90	203%
				Biosera/Panjon	Totaryl /Cachet	

Drugs for Gastrointestinal Symptoms and Diseases						
61.	Rabeprazole	No	No.	0.45	9.25	2055%
				Rabera, Jenburkt	Happi, German remedies	
62.	Famotidine	Yes	Yes	0.24	3.75	1562%
				Famtac, Nicholas Piramal	Autidine, Aurobindo	
63.	Domperidone	No	Yes	0.25	3.29	1316%
				Vomistop/Cipla	Gastractiv/Ethnor	
64.	Ondansetron	No	Yes	2.5	19.2	768%
				Anset,Depone	Zondan,GSK	
65.	Omeprazole 20 mg	No	Yes	0.58	4.32	744%
				Omecip, Cipla	Omez, Dr. Reddy's	
66.	Metoclopramide	No	Yes	0.5	1.06	212%
				Reggi, Shalaks	Perinorm,IPCA	
67.	Ranitidine	Yes	Yes	0.54	1.06	196%
				Consec, Jagsonpal	Ridcer, Gufic	
Drugs Used in Skin Diseases						
68.	Clobetasol propionate 0.05%, cream 15 g	No	Yes	11.13	32.50	292%
				Powercort, Glenmark	Tenovate, GSK	
69.	Povidone iodine Oint 5% 15 gm	No	yes	11.0	29.75	270%
				Alphadine, Nicholas piramal	Betadine, Win (29)Medicare	
70	Silver sulfadiazine 1% cream	No	Yes	9.50	25.00	263%
				Silvirin, Raptakos Brett and co	Ceptidar, Lupin	
71	Gammabenzene hydrochloride 1% 100 ml	No	Yes	15.78	24.00	152%
				Bexarid, Shalaks	Welscab, Bliss	
Drugs Used in Respiratory Diseases						
72.	Salbutamol 4 mg	Yes,	Yes	0.16	0.97	606%

				Asmanil, Inga	Ventorlin, GSK	
73.	Beclomethasone metered dose inhaler. 100 mcg/puff, 200	No	Yes	150.00	223.47	148%
				Bevent, Kresp	Becoride, GSK	
Drugs Used in Allergies						
74.	Cetrizine 10 mg	No	No	0.27	2.85	1055%
				Cetcip, Cipla	Zyncet,Unichem	
75.	Chlorpheniramine maleate	Yes	Yes	0.05	0.2	400%
				Cadistin, Cadila	Cofton, Cipla	
Drugs Used in Epilepsy						
76.	Phenytoin 100 mg	No	Yes	0.21	1.19	566%
				Epileptin, IDPL	Dilantin, Parke-Davis	
77.	Gabapentin 400 mg	No	No	11.95	41.24	345%
				Epileptin, IDPL	Dilantin, Parke-Davis	
77.	Gabapentin 400 mg	No	No	11.95	41.24	345%
				Gabapin, INTAS	Neurontin,Parke-Davis	
78.	Clonazepam 2mg	No	No	1.50	5.09	339%
				Epcon/Laa pharma	Rivotril/Nicholas piramal	
79.	Carbamazepine 200 mg	Yes	Yes	0.87	1.84	211%
				Cizetol, Cipla	Tegrital,Novartis	
Drugs Used in Psychiatry						
Antidepressants						
80.	Fluoxetine 20 mg	No	Yes	1.3	2.5	192%
				Flupar, Mejda	Prodep, Sun	
81.	Amitryptiline 25 mg	No	Yes	0.83	1.79	215%
				Eliwel, Sun	Trytomer, Merind	
Anxiolytics, sedatives						
82.	Alprazolam 0.25 mg	No	Yes	0.09	1.08	1200%
				Alprazolam, Shalaks	Anxit, Micro labs	
83.	Diazepam 5 mg	No	Yes	0.29	1.76	606%
				Dizep, INTAS	Valium, Piramal healtcare	

Antipsychotics						
84.	Clozapine	No	No	0.67	15.9	1492%
				Clomach, La Pharma	Leponex, GSK	
85.	Chlorpromazine 50 mg	Yes	Yes	0.28	0.9	321%
				Sun prazin, Sun	Chlorpromazine, Sun	
86.	Haloperidol 1.5 mg	No	Yes	0.42	1.1	261%
				Trancodol,Intas	Serenace,RPG	

Discussion of Survey Findings

Our survey of retail prices reveals:

- Complete anarchy of drug prices that can be explained only by profiteering of drug companies who hold themselves accountable probably only to their shareholders.

- There are tremendous variations in prices of drugs in all categories, which are inexplicable on any other grounds than a lax regulatory system and rampant profiteering by the drug companies at the patient's expense.

- The tremendous variation inflates the treatment costs manifold whether the patient buys a simple drug like paracetamol, a drug for an infection, a drug for hypertension, diabetes, or cancer. The difference between brands is to the extent of 2000%. The per unit cost of this variation can vary from tens of rupees for an antibiotics, hundreds of rupees for an anti-cancer drug, and thousands of rupees for a drug like streptokinase used for heart attacks. For a patient with a chronic ailment like diabetes, hypertension, ischemic heart disease, epilepsy, the per unit variation seen between drugs can translate into thousands of rupees spent or saved per year as the case may be. For an acute ailment like a serious infection, or a heart attack, the difference between brands could mean the difference between affordability or unaffordability and therefore between life and death.

- The reality of drug prices in India as seen in this section is in total contrast to the myth of a well-regulated market with a rigorous implementation of price control order in the price controlled drugs and watchful monitoring of prices of price de-controlled drugs as the government claims. Companies are flouting drug price control orders with impunity. Drug prices of different brands vary inexplicably from 200% to 2000%. This inexplicable situation has not elicited any coherent response from the government, which is itself inexplicable. The situation in fact clearly calls for a greater role for governmental regulation, and definitely not lesser, as is being considered by the government.

What are the Real Costs of Drug Production?

- The costs of drug manufacture are in fact quite low: if you take the ex-factory costs as a percentage of the retail prices of drugs (see Chapters 9 and 10 for a detailed calculation of costs).

- The difference between tender prices in large tenders and the retail prices in the market (see Chapter 1, Table 3) indicate large profits for the companies and the pharmaceutical trade, which are not usually seen in the market for other commodities. A drug like albendazole, which is available for Rs.11 per tablet in the market, its tender price quoted by Cadila, was a mere 22 paise, which is 2% of the market price. A drug for hypertension like atenolol, which may cost Rs.1.75-2.00 in the market, was quoted at 8 paise, which is less than 5% of its retail price. The difference is effectively the margins used for fancy marketing costs and margins for wholesalers and retailers.

- Doctors too must share a large part of the blame for inflated drug costs. Being passive recipients and sometimes active solicitors of the largesse of drug companies, they confound the situation by making the companies add on the cost of the free gifts, free lunches, to the cost price of the drug. By not prescribing the most cost-effective medication they do not allow market forces to act in the interests of patients.

Do Quality Standards Make Drug Prices High?

People also believe that broadly speaking large and well known manufacturers charge a higher price which might be indicative of higher quality, especially in a country like India where the quality control mechanisms leave a lot to be desired, and consumers are unsure of the quality of the product that they buy. But this assumption is not wholly true either.

Consider the following incidents involving drug companies and regulatory authorities that involve a bypassing of quality and ethical norms[9]:

a) **Boehringer-Mannheim and Cotrimoxazole** "The FDA in Maharashtra ordered a nation-wide recal of the antibacterial drug Comsat Fore, a brand of Cotrimoxazole, of Boehringer-Mannheim, (India) Limited when it was found to be contain the antidiabetic ingredient Glibenclamide as a result of mix-up in raw materials on the shop floor of the manufacturing plant. Rather than cure infections, the tablets caused a drastic fall in blood sugar and blood pressure, and 62 people turned critical after using it at an eye camp in Ahmednagar on August 16, 1996. Although the deadline for recall expired on September 5, the drug claimed two lives in Kolar, Karnataka, five days later. The company's Managing Director left India for Canada. The Maharashtra FDA has been reported to have opined that the multinational company is over 125 years old and that its reputation had to be considered before taking any precipitate action. Is this ethical?"[10]

[9] For more on this and related issues, see *A Lay Person'sGuide to Medicine*. LOCOST, Baroda, 2000.
[10] Quoted in "Changing Era of Social Responsibility and Corporate Ethics in Indian Pharmaceutical Industry" by
H. Indurkar at http://www.aims.org.in/aims/articles/Theme%20I%20-%20Corporate%20Values%20&%20Ethics/AIMS-IndurkarPAPER%2001.doc

b) Letrozole Affair: Over 400 women were allegedly used as "guinea pigs" by some researchers to test anti-cancer drug, Letrozole, for curing infertility through induction of ovulation. The clinical trials allegedly took place without the permission of the Drug Controller General of India at private clinics in places like Delhi, Nagpur, Hyderabad, Kolkata and Jodhpur. Letrozole belongs to Schedule G of the Drugs and Cosmetics Rules and can be sold only against prescriptions from cancer specialists. Based on documents submitted by the innovator of the drug, Novartis, US Food and Drug Administration and British Medicines and Healthcare Products Regulatory Authority have labeled it as embryotoxic and fetotoxic at miniscule doses. [See news report "Doctors in India prescribe unapproved fertility drug" in the *British Medical Journal*, BMJ 2003; 327:768 (4 October)]

c) The Case of Nimesulide

" The Indian government has admitted that drug formulations unapproved by India's drug regulatory agency and not evaluated for effectiveness are prescribed and sold across the country. The unprecedented admission from the MOHFW emerged at a court hearing on nimesulide, a controversial non-steroidal anti-inflammatory drug prescribed in India to treat fever and pain" (BMJ 2003; 326:70). The Drug Controller of India has blamed states' drug regulatory officials for issuing manufacturing licences despite the absence of marketing approvals from the central health ministry. In an affidavit the drugs controller's office said it had asked a panel of experts to examine whether nine of these fixed dose combinations could be justified." (Source: "Drug linked to child deaths is still available in India" in British *Medical Journal* 2003; 326:1286.).

d) Justice Lentin's Observations

Nearly 18 years ago Justice Lentin had documented a similar nexus between officials of Maharashtra FDA, drug industry and certified quality labs. .

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"The Commission exposed the understanding between manufacturers of sub-standard drugs and the upper echelons of the FDA. The protection these manufacturers received from FDA, the flagrant violation of laws in issuing licenses, deferring prosecution of errant manufacturers and ministerial interference at every stage.

- Some startling facts that were revealed in the course of the hearing - between January and September '86, 582 formulations were found to be substandard with hardly any action taken against the offenders, many of whom were the "reputed" big companies.

- 300 formulations were found to be substandard between Feb. '87 and July '87, but they continued to be sold.

- 20% of drug samples drawn were found to be substandard and yet follow up action on the part of FDA had been almost non-existent.

- Several summons to the State Government and FDA to produce a missing file evoked no response. When a newspaper reporter finally unearthed the file, it contained evidence of FDA manipulations to pass a drug formulation manufactured by Glindia (formerly Glaxo Laboratories), which was not of standard quality.

e) Glaxo Sells Expired Drugs – the Glaxo Scandal

Even leading drug manufacturers like Glaxo have been incriminated in this regard, when they were found to be selling expired drugs to a scrap dealer instead of destroying them. We know of no other country in the world where an extreme step like consideration of a death penalty has been proposed as a deterrent to the problem.

The Maharashtra State Food and Drug Administration (FDA) ordered the closure of Glaxo (India), a British multinational company's production in its Worli factory in Bombay for 10 ten days in March 1994 for violating the provisions of the Drugs and Cosmetics Act and the rules of FDA. In June 1993, the FDA found that Glaxo, instead of destroying rejected drugs had authorised a scrap dealer to collect the substandard drugs from its premises. These drugs were then recycled and sold in black market, putting unwary consumers to grave risk

The FDA seized large stocks of unlabeled drugs like Betnesol, Viteneuron and Prepalin Forte injections manufactured by Glaxo, rubber stamps and also large stocks of coded and plain Glaxo labels from the scrap dealer's godown in Dharavi slum area. Following the discovery of labelled and unlabeled drugs, coded and blank labels, and printed cartons in the factory's unit in the presence of the company's quality assurance manager and the general manager, the company was issued a show-cause notice. On June 14, 1993, FDA suspended Glaxo's licence to manufacture various drugs for ten days from July 15 to 24, 1993. However, Glaxo appealed to the State Health Minister against this order.

f) Selling of Substandard TB Drugs by Reputed Companies

We quote from the *Indian Express* of Aug 4, 2003:

RANCHI, AUGUST 3: The Jharkhand Drug Administration has imposed a state-wide ban on the use and distribution of five medicines manufactured by Lupin Ltd, Aurangabad, Nestor Pharmaceuticals Ltd, Faridabad and Pure Pharmaceuticals Ltd.

These medicines — Pyrazinamide IP-750mg, Isoniazid (Tab) IP-300mg, Pyridoxinc IP-5mg, Ethambutol (Tab) IP-600mg and Rifampicin (Cap) — are prescribed to TB patients and were supplied to hundreds of government-run hospitals in the state by the Union Health Ministry last year.

State Drug Controller Vinay Mohan Prasad said: ‘‘Samples were collected by drug inspectors from Ranchi, Hazaribagh, Dumka and Dhanbad. Laboratory test confirmed the suspicion that these medicines were of substandard variety.’’

In his July 28 letter — circulated to all civil surgeons, superintendents of state-run hospitals in 22 districts of the state and Jharkhand Chemists and Druggists’ Association (JDCA) — Prasad has stated that ‘‘the ban is being imposed on use and distribution of the above medicines’’.

Person incharge of SL, Dr. B.N. Sinha, in his March 23 report to Prasad states: ‘‘In the opinion of the undersigned, the samples selected ‘do not conform’ to the claims in respect of the test performed’’. Explaining Sinha’s report, Prasad said: ‘‘This means these medicines lack potency as per the claims made by the manufacturers.”

g) Diethylene Glycol Poisoning Revisited

> The specific incident of diethylene glycol poisoning in Gurgaon is shocking for its lack of care. The evidence in the episode was pointing to a common drug exposure. But the district and state drug controller gave the suspected batch of drugs a clean chit. Yet the doctors persisted…
>
> > " the district and the state drug controller had tested many samples using thin layer chromatography before a sample of medicine tested positive for diethylene glycol at the Central Drug Testing Laboratory, Calcutta…. This indicates that thin layer chromatography alone may not identify contamination with diethylene glycol. On the other hand gas liquid chromatography or other appropriate methods are not available in all the laboratories that may be asked to test medicines. The failure to detect the contamination using thin layer chromatography had an important bearing on these cases. Once contamination was suspected and the samples were sent for testing, the number of cases suddenly declined. After the samples were declared not to be contaminated, 6 more cases occurred. Further cases were only stopped because scientists suspected contamination and insisted that the suspect medicines should not be used unless found to be uncontaminated using gas-liquid chromatography."
>
> This clearly illustrates that the district and state drug controller could not detect the lethal contamination of the drug with diethylene glycol and it was only the Central Drug Testing laboratory at Kolkata that could detect it. Is this not a serious matter in a case where more than 30 innocent children died because of the greed and unscrupulouness of a drug manufacturer and the lax regulatory framework in the country?[11]

More recently, the entire TB drug consignment of rifampicin capsules exported by a leading anti-TB drugs manufacturer was returned by the authorities in south Africa after detection of poor blood levels with the drugs.[12]

Many other instances may be given of well-known companies in India and abroad whose products have failed and continue to fail routinely. Quality is not a prerogative, if at all, of big companies and in fact there is no straightforward correlation observed between the size of a drug company and its quality consciousness

At the international level it is an Indian company, which opened the eyes of consumers, governments and activists worldwide to the reality of drug prices. In 2001 CIPLA created a stir by proposing to supply the triple drug combination for HIV disease/AIDS to the Medicines Sans Frontieres (MSF) and African governments at $350 per patient per year. These combinations made by the US Pharma companies cost $10,000-15,000 per patient per year on the other hand. This act has suddenly opened the eyes of drug activists and those concerned for health on the amount of overpricing on drugs internationally as compared to drugs made in India. However it is an irony that these drugs made and marketed by Indian companies, which are seen as affordable elsewhere in the world, are not affordable for even the middle class in India.

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[11] Singh, Jagvir, Dutta, A.K., Khare, Shashi *et al*. Diethylene glycol poisoning in Gurgaon, India, 1998. *Bull World Health Organ*. [online]. 2001, vol.79, no.2 [cited 23 May 2004], p.88-95. Available from World Wide Web: http://www.scielosp.org/scielo.php?script=sci_arttext&pid=S0042-96862001000200002&lng=en&nrm=iso

[12] 'Cape Town study faults Lupin's TB drugs' at http://www.expresshealthcaremgmt.com/20020731/edit4.shtml

We have also have more recently the case of drug imatinib mesylate (brand name of Novartis 'Gleevec'), made by Novartis, was made at one-tenth the price by the local manufacturers in India. The company Novartis has argued in the courts that its EMR on the drug prohibits others from making it.[13]

Drug companies have often claimed high prices because of R &D costs. This argument by and large till recently was not applicable for Indian drug companies. The high prices of AIDS drugs and the anti-cancer imatinib mesylate, and the possibility of drastically lowering its costs by 3-10 times, only highlight the need for clear norms and data about how much really does research cost, what ought to be the legitimate apportioning of research costs into pricing of a drug, especially when much of the research leading upto the patenting of a drug (for example in the case of imatinib mesylate) was done in public funded organisations.[14] An argument that is equally valid against the high price of Hepatitis B vaccine of Shanta Biotech where the original technology was developed at one of the Hyderabad-based CSIR organisations which is funded by the Government of India.

THERE IS NO OTHER SITUATION AKIN TO THE PURCHASE OF DRUGS BY A PATIENT WHERE

- The consumer may have no knowledge about the goods he/she is purchasing,
- Where the goods can be purchased only on the written recommendation of a third party (who may charge you heavily for doing so), no other situation where the goods are purchased in such distress,
- Where the result of non-purchase of the goods may be death or disability.
- There is no other situation where expensive gifts and heavy discounts are offered to those recommending and stocking a particular good and none offered to those who purchase them.
- There is also no other situation in which a particular company making a particular product can have exclusive rights over marketing and manufacture for a period of 20 years.

Arguments that the 'market would take care of prices' have been shown to be hollow in the case of medicines and health services (see Chapter 1 and Chapter 4). To equate drugs

[13] As we go to the press (August 2004), the Cancer Patients Association of India has challenged the grant of exclusive marketing rights (EMR) through a writ petition in the Supreme Court of India. The Supreme Court has issued notice in the matter. The Petitioners have filed this petition in public interest under Article 32 of the Constitution of India on account of the violation of the right to health and equality of cancer patients suffering from Chronic Myeloid Leukemia (CML).

[14] See for a taste of the debate: 'America's other Drug Problem' by Arnold S. Relman *and* Marcia Angell in the *New Republic, Dec 16, 2002.* Also available at http://www.drugawareness.org/pdf/tnrdrugpiece.pdf.
See also: July 23, 2001. Public Citizen. Rx R&D Myths: The Case Against the Drug Industry's R&D "Scare Card." And related counter arguments at http://www.cptech.org/ip/health/econ/rndcosts.html

with other consumer goods is a dangerous idea. How can a consumer choosing TV sets at leisure be equated with a patient with tuberculosis buying drugs for his/her illness at a chemist store or a patient with a rabid dog bite buying a vaccine that he/she must buy.

Three other issues of contention need to be addressed even at the risk of belaboring the point.

What is the extent of price control of medicines in India? In fact if the list of top selling brands is taken (see Chapter 11, 'Anomalies in Drug Pricing') only 36 out of 300 formulations are under price control, which also means that already in the case of nearly 90% of the drugs a free market already exists where there is no stipulated retail price. We have seen from the data presented in this chapter (as also from Chapters 1, 2 and 4) that this is not in a true sense a free market operating such that the consumer benefits by getting the lowest prices of medicines. Competition as we have tried to show elsewhere in this book does not work in the case of medicines and health services. The box below giving details of the case against Johnson and Johnson is only the tip of the iceberg.

CBI case against Johnson & Johnson

(The Tribune, Jan 25, 2002)

New Delhi, January 24

The CBI has registered a case against two Mumbai-based firms, including multinational Johnson and Johnson Ltd, for allegedly causing Rs 50 crore losses to the government besides cheating consumers by overpricing drugs.

Johnson and Johnson was found to be allegedly availing of exemption from price approval provided to small scale drug units by "fraudulently" floating a small scale unit N.R. Jet Enterprises and showing that such drugs and medicines were not manufactured by it, a CBI press note here said.

During investigations, the agency found that Jet Enterprises was controlled by employees of Johnson and Johnson and some of the products being manufactured by it were earlier being produced by the multinational, the release said that adding these medicines were still being promoted as products of Johnson and Johnson.

The CBI alleges that one such medicine, Raricap, was earlier marketed by Johnson at a retail price of Rs 16.24 per 40 tablets as fixed by the government under the provisions of the Drug Price Control Order 1995. However, the said product is being now manufactured by Jet Enterprises and is being sold at a retail cost of Rs 55.

Johnson and Johnson officials were not immediately available for comments

Is price control effective? The violations of price control order and the astronomical variations in drug retail prices presented in the tables are hardly evidence of effective regulation of the market by the government.

Does being a WTO signatory put a brake on the price control as an instrument of public policy? Is it incumbent on us to do away with price control post-2005? There is no such obligation under the WTO regime. We shall only have to comply with the international agreements on product patents with the option of compulsory licensing. The Government of a Sovereign Democratic Republic is free to impose price control. That is the spirit of the Doha agreement as well as Article 8 and 31 (b), among others, of WTO/TRIPS[15].

[15] C.M. Correa. *Uruguay Round and Drugs*. WHO Task Force on Health Economics/Action Programme on Essential Drugs, Geneva, 1996. The official WTO booklet for Seattle had this to say: "Moreover, the obligations of the TRIPS Agreement do not stand in the way of price controls and similar types of measures for pharmaceuticals." Quoted by James Love at http://lists.essential.org/pharm-policy/msg00320.html

CHAPTER 3

DRUG PRICE CONTROL: PRINCIPLES, PROBLEMS AND PROSPECTS

-Chandra Gulhati[1]

Points for deliberations: Why regulate drug prices? India: Is it the only country with price fixation? Do Indian pharma companies make adequate profits? Are Indian drugs cheapest in the world? Can the nation rely on competition to check drug prices? Is system of selection of medicines and brands by Indian doctors rational? Misconceptions on the so-called "Essential Drug List." Industry's New"Innovative" arguments.

Why Regulate Drug Prices?

One way or the other all prices of all goods and services are subject to some sort of price regulation either through state's intervention or other mechanisms including competition, demand-and-supply equilibrium, purchasing power of people just to mention a few. One argument often heard is why should state control drug prices when prices of other commodities are not controlled. First of all it is incorrect to say that the state does not intervene in regulating other prices. Some examples:

Bus and taxi fares: decided, monitored and controlled by transport authorities.

- Telephone rates: Determined by Telecom Regulatory Authority of India (TRAI)
- Insurance premium: controlled by Insurance Regulatory & Development Authority (IRDA).
- Electricity tariff: Decided by the state-level Electricity Regulatory Commissions such as DERC in Delhi.
- Interest rates: Both chargeable and payable by financial institutions and corporations are decided upon by the Reserve Bank of India (RBI).

Surely medicines are not less important than telephones call charges or insurance premia. So why should the state not ensure that they are available at fair, affordable prices?

For the sake of argument even if state was not regulating other prices, there are very strong reasons to have some sort of control over drug prices. Why?

Because unlike all other items, drugs have no alternative. For example when onion prices went up few years ago, people started using lesser quantity to suit their pockets. One cannot do this with drugs.

If rice becomes unaffordable by a class of people, one can use wheat, bajra or some other grain. If someone cannot afford a car, he can use scooter or even bicycle or still worse just walk. However there is no alternative to medicines.

Unlike other items, the need to buy drugs is immediate, involuntary and obligatory - one can avoid buying clothes at least for some time but not drugs. Whether one begs, borrows or steals, money has to be arranged to reduce suffering and save human life.

[1] The author is the Editor of MIMS India. This is a revised version of a paper under the same title published earlier in the *Medico Friend Circle Bulletin*, June-July 2004.

Medicines are the ONLY item on the face of the earth, where the decision to buy is not taken by the purchaser but by a third party i.e. prescriber. Therefore if the prescribers and the producers join hands to take advantage of patients' vulnerability, there is no one to stop them except the state.

Complaint: India is the Only Country where Drug prices are Controlled

Price control is required only when patients have to pay from their own pockets. In India, 80% of the population is dependent upon private medicine and hence health costs are a big drain on people's pockets.

There are other factors that come into play. Drugs constitute 7% of the healthcare costs in USA while in India it is over 40%; so the relative impact is higher in India. The mere fact there is no DPCO in US or UK or elsewhere does not mean that there is no price regulation in these countries. Some facts:

United States: Nearly every one is insured against illness. Cost of drugs are reimbursed by insurance companies who keep an eagle's eye on both, prescriptions and prices. If a doctor is found to be unnecessarily prescribing high cost drugs when cheaper alternatives are available, he can loose insurance business. This in effect means he will have to give up profession. Similarly, manufacturers cannot charge more than what they are charging in other countries.

United Kingdom: The entire medical costs are met by the Government through National Health Service. Manufacturers have to negotiate prices with the government. In fact the price control is more rigorous in England than India because there is only one buyer. The NHS pays substantially discounted prices on all medicines. For example Buscopan is sold to NHS at a discount of 42% over the MRP. In any case, individual patients are not concerned.

Belgium (as an illustration of European Community countries): Every resident, including foreigners, get total reimbursement of all medical costs from three government-controlled "mutuelle" who compete with each other but their annual subscriptions are decided by the state and are most reasonable.

The effectiveness of the above measures can be gauged from the fact that US Government is currently prosecuting Glaxo Smith Kline for billion of dollars for overcharging on ranitidine and thus "cheating" USA.

On the other hand in India, the entire system is based on MRP. What about the transfer prices from a related manufacturer or on loan license? There are cases where there is huge difference between the transfer price (price charged by actual manufacturers/loan licensees to the marketers/manufacturer and the MRP.

Complaint: Indian Manufacturers do not make Adequate Profits

Nothing could be farther from truth. Some facts:

- On the nation's Stock Exchanges, pharma shares have always remained on very high side compared to other sectors including manufacturing companies be it Siemens or Reliance. Ranbaxy's Rs. 10 share is being quoted at over Rs. 1200 (December 2004). Promoters and their family members of Sun Pharmaceuticals who allocated themselves shares for Rs. 1000 in 1994 can now sell their shares for Rs. 600,000 (December 2004). If the profits were not handsome, why would investors buy these shares at such high prices?

- A look at the balance sheets of pharma companies shows their profitability is one of the highest and beats nearly all other sectors except perhaps software. In fact most companies boast of 20 to 50% increase in profits than previous years, year-after-year!

- India has the highest number of pharmaceutical manufacturers in the world: over 17,000. Surely no business minded person would enter a field where profits are not adequate.

- Non-pharma large business houses are eager to enter drug business. Some examples: JK Tyres, Camlin ink, Raunaq group, LG Electronics

- Pharma manufacturers pay one of the highest salary packets to their employees. The marketing heads of many pharma companies get more than Rs. 25 lacs+ annual pay packet with other perquisites. Such salaries are unheard of in other manufacturing sectors.

- There must be substantial profits to allow the manufacturers to offer bonus schemes to chemists including some DPCO-controlled formulations. Examples: IPCA was giving one strip free with every 10 strips of Lariago (chloroquine). Cipla was giving one strip free with every 4 strips of Novamox brand of amoxycillin (which translates to 25% discount). There have also been bonus schemes for metronidazole (10+2) and ampicillin (10+1). On Cifran (ciprofloxacin) Ranbaxy is (September 2004) giving 74% extra discount + a camera as a gift. (No wonder NPPA has initiated recovery proceedings for excess price charged by the Company). FDC is giving 54% extra discount (July 2004) to retailers on Zilee 250/500 (levofloxacin). To beat them all, Mankind has been giving 23 strips free with every 10 strips bought of Manforce (tadalafil) translating into 75% discount! The manufacturers explained that they had to liquidate unsold stocks and hence resorted to bonus schemes. This is blatant bribe to chemists to substitute brands, which is illegal under Drugs & Cosmetic Rules!

- India is THE ONLY country where people with very modest means have produced huge amount of wealth from pharmaceutical manufacturing business in the past two decades. A milkman and a retail chemist have joined the select league of multi-billionaires from pharma business. As per Forbes magazine the ten top richest persons out of 40 in India are from the pharma industry.

Surely, the pharma business is highly profitable.

Claim: Drug Prices in India are Among the Lowest in the World

Nominally yes but then how does one compare the purchasing parity of various currencies. Is US$ 1 in USA worth Rs. 45 in India in its purchasing power? Certainly not. Exchange rates are determined based on demand and supply of foreign exchange, not their actual worth. As per UN study, Indian currency is 5.3 times higher in its purchasing parity compared to its exchange rate of Rs. 45 with US dollar. In other words a dollar's real worth is about 8.5 rupees. It is because of this reason that UN employees when transferred from, say, USA to India do not get their emoluments based on bank's exchange rate.

In the United States, the minimum wage is US $ 6.50 per hour; in UK about GBP 5. An unskilled person needs to work for less than 10 minutes to buy 10 tablets of paracetamol. In India a person will need to work for at least one hour to buy equivalent amount of the same drug, which incidentally is one of the cheapest. So the cost of the cheapest drug is 600% more in India compared to the United States.

While seeking higher prices, manufacturers often resort to quoting figures from developing countries to compare prices. These arguments are merely self-serving and misleading. Reasons?

1. Unlike India, most countries accept the Convention on patents and hence pay royalties for research expenditure to innovators if the drugs are produced locally. Naturally the prices are higher. Why should this be taken as reason to justify higher prices in India which had not accepted the patent regime and manufacturers did not have to pay even one paisa as royalty?

2. As explained above currency parity is difficult to establish and prices based on exchange rates are deceptive.

3. Standards and cost of living are different. How does one compare drug prices in Malaysia – with far higher income levels and standard of living - with India?

4. Except for Nigeria, Egypt and Jordan, there is hardly any pharma manufacturing industry in other developing countries of Asia and Africa that are dependent on import of drugs from other countries. Naturally the prices are higher.

5. Custom duties, where applicable, increase the prices. This is not applicable to India because the drugs are locally manufactured.

6. Chemists margin are different in different countries and have an impact on retail prices.

7. Local taxes are different that have an impact on prices.

8. Local rules governing pharmacies are different. For example in some countries, fully qualified B.Pharm graduates have to man drug stores; therefore the cost goes up. In India more than 60% shops do not have even a person with D.Pharm. Many states allow 5-year experienced shopkeepers to be classified as "pharmacist." Hence the labour costs are very low.

9. Even if the above reasons were not operative, how does it matter if the prices are higher, or lower, in other developing countries? After all prices in India are dependent on local manufacturing costs, local margins, local distribution costs and local purchasing power. The fact that some other governments of some other countries are less than vigilant or less than willing or powerless with respect to drug prices does not mean that India should be equally irresponsible. In most cases, these figures are given merely to complete documentation in government files so that obliging officers can justify higher prices.

10. India with its huge population and market has advantage of “economy of scale” and even if all other factors were not applicable, the prices have to be lower compared to other developing countries.

Industry’s Suggestion: Competition Should Decide the Drug Prices

Let us first look at some of the prices of same molecules sold under different brand names. The variations are miles apart. Some examples:

- Fexofenadine 120mg: one tablet of Alernex (Dabur) costs Rs. 4 while Allegra (Aventis) is priced at Rs. 8 - the difference being 100%.

- Two brands of cetirizine are priced at Rs. 2.10 and Rs. 3.15 per tablet: a difference of 50%.

- Gliclazide: Lycazid (Jagson Pal) is priced at Rs. 31 (for 10 tablets) compared to Rs. 59 for Diamicron (Serdia) a difference of over 190%.

- The difference in the cost of Risperidone is beyond imagination: Less than Rs. 18 for all manufacturers except Johnson & Johnson that costs Rs. 135! A difference of 770%.

- Amlodipine prices are widely different: Amlodac 10mg is priced at Rs. 18.15 for 10 tablets while Amlovas of equal strength costs Rs. 35 for 10 tablets – a gap of 200%.

There are scores of other examples. Since no manufacturer would be selling at a loss, it is obvious that huge profits are being made.

Normally the sale of cheaper brands should not only be substantially more than costly brands but expensive brands should die a natural death in due course. Let us look at the facts and figures:

- As per ORG figures, Cyclovir (Zydus) brand of acyclovir with the therapy cost of 812 rupees had a total sale of Rs. 57 lacs over a 12-month period compared to Rs. 3.17 crores for more expensive Herpex (Torrent) brand (cost of therapy: Rs. 1,666). So poor was the response by prescribers to the low price product that it had to be discontinued.

- Diamicron (Serdia) brand of gliclazide at Rs. 59 for 10 tablets was worth Rs. 7 crores against the cheaper brand, which had a measly sale of Rs. 66 lacs (Glidiet). The medicine is to be taken for life.

- The most expensive brand of enalapril (Envas) sells far more than cheaper but equally reputed brands of other manufacturers. The cost difference is over 33%. It is a life long medicine

- Obviously, doctors are oblivious of cost to patients. A more logical explanation is that doctors get easily “influenced” by manufacturers who have the capacity to spend large sums of money on aggressive promotion and offer huge incentives to "right" prescribers. Some examples:

- In the past eight years, a south Delhi based surgeon has been sent on vacation to Switzerland by a well known Delhi based pharma Company every year. Quid pro quo: he prescribed only the obliging Company's products. In the case of antibiotics he went one step further. Instead of 5-7 days, the patients were made to swallow the bitter pill for 10 days.

- Johnson & Johnson which produces epoetin alfa (life saving for kidney transplant patients) was gracious enough to sponsor 300 kidney specialists to visit Singapore for three days. Result: its brand has the highest sale.

- Ranbaxy sponsored the visit of about 400 prescribers to Bangkok.

- Glaxo has given thousands of refrigerators to chemists as “gift”.

- Under such circumstances, who except the state can protect the interests of patients?

Selection of Medicines and Brands

Unlike the developed countries, there are no standard guidelines on the selection of medicines. For example in England, the National Institute of Clinical Excellence (NICE) issues periodic consensus guidelines on the exact options, in correct sequence, for treatments of various diseases like Asthma, Hypertension, Diabetes etc. Such system has several advantages: firstly, it is scientifically valid; secondly, it is cost effective.

In India every doctor decides on his own which brand of which medicine to patronize. Not infrequently the choice is scientifically inappropriate and financially costly. Let us look at some examples:

- The correct treatment of chlamydial genital infection is tetracycline (cost Rs. 14). Yet most, if not all doctors are somehow "persuaded" to prescribe ofloxacin (cost Rs. 100) by manufacturers. Why does it happen? Because high profits lead to higher promotional efforts and larger prescriptions.

- Many clinical trials have established that there is insignificant difference in the efficacy of omeprazole (cost Rs. 38 for 10 tablets) and pantoprazole (cost Rs. 65 for 10 tablets). Yet large number of doctors prescribe pantoprazole apparently influenced by manufacturers.

- It is the same story for enalapril (Rs. 14 for 10 tablets of 2.5mg) and perindopril (Rs. 97 for 10 tablets). Incidentally against a price difference of 1:7 in India, the difference in UK is only 1:2 between the two molecules.

Why does this happen? Because pharmaceutical manufacturers in India have tremendous influence over prescribers. The policy framework of DPCO and its implementation is not helpful at all; in fact it is making the matter worse. Due to various rules and regulations, mostly the axe of DPCO falls on what we call as the reference (initial) molecule which gets price controlled, leaving the related molecules to mint money for producers.

The industry is quick to provide selectively selected "scientific evidence" based on isolated trials, often defective and deceptive, to prove that their molecule is "superior" to reference molecule. Often the alleged superiority, even when present, is 1-2% but costs 200-300% more.

The solution lies in controlling the profits on all molecules belonging to the same class as well as other drugs used in the same therapeutic area. For instance:

If the price of diazepam is fixed leaving other benzodiazepines uncontrolled, then prescriptions will shift to them.

If the price of chloroquine (costs less than one rupee per tablet) alone is fixed leaving other anti-malarials untouched, then prescriptions will shift to uncontrolled agents such as mefloquin or artemether. The danger is not only that poor patients will pay more (artemether costs Rs. 18 per tablet) but there will be long-term scientific repercussions. For example, mefloquin or artemether are reserve drugs and should only be used for chloroquin-resistant strains of malarial parasites or in cerebral malaria. If they are indiscriminately consumed, the day is not far off when all the malarial parasites in India will become resistant to all agents.

Similarly if ranitidine price is controlled, prescriptions will shift to other H-2 receptor antagonists like famotidine or to sucralfate or omeprazole and its related molecules.

A noteworthy example is that of phenylpropanolamine (PPA) v/s psuedoephedrine. Actifed, a cough and cold remedy of Glaxo is an international brand. All over the world it contains pseudoephedrine while in India it contains phenylpropanolamine. PPA is known to cause strokes and hence been banned or discarded in all advanced countries. Coldarin issued front-page ads to inform readers that its product was free from PPA. Yet recently they themselves have changed their own formula by using the discredited, dangerous PPA. Why? Because PPA is cheaper while pseudoephedrine is not only expensive but under price control. Since both are decongestants, they should be subjected to similar price controls or remain out of price control. (Not to mention the fact that DCGI failed to ban PPA that stands discarded in the West.)

The cost price of 10 tablets of nimesulide is Rs. 1.40; its MRP is in the range of Rs. 26 to Rs. 29. Despite the fact this US-discovered medicine is not permitted to be sold in America and other advanced countries (e.g. Britain, Canada, Australia etc.) it has a huge sale in India on the back of aggressive promotion. In India it is permitted to be administered to neonates while it has been banned for use in children below 12 years by European Medicine Evaluation Agency.

Cough syrups and tonics have a total sale of over 800 crores including the so-called Branded generics - a typically Indian nomenclature that does not appear on ORG retail audit. These are supplied to chemists to sell without prescriptions, particularly in semi-urban and rural areas. A bottle of cough syrup with a printed price of Rs. 24 is given to chemists for Rs. 10. He can make a profit of over 150%. Producer's cost is below Rs. 7. Similarly a bottle of tonic with MRP of Rs. 50 is sold to chemists for Rs. 22. Its actual cost is less than Rs. 10.

There are many diseases that require drugs belonging to several therapeutic areas. For instance H. pylori eradication needs a proton pump inhibitor (omeprazole or lansoprazole or pantoprazole), an antibiotic (amoxycillin or clarithromycin or oxytetracycline) and an imidazole (metronidazole or tinidazole or

secnidazole). It would serve no purpose to control prices of one PPI, one imidazole and one antibiotic because prescriptions will invariably shift to uncontrolled more profitable drugs.

Misconception on "Essential Drugs"

Unfortunately, the well-intentioned nomenclature of "Essential Drugs" coined by WHO several years ago in another context is sought to be used by the drug manufacturers to claim that medicines that are not included in the Essential Drugs list should be outside the price control mechanism. Nothing could be more unfair.

- All drugs are essential for specific patients. Is it fair to control the price of chloroquine that costs hardly 80 paise and is used for 3 days since it falls in the Essential Drug List and leave out leflunomide that costs Rs. 45 per tablet and is to be taken daily by patients unfortunate enough to suffer from crippling rheumatoid arthritis? If any thing, leflunomide needs price control even more than chloroquine.

- Is streptokinase (Price Rs. 2,500) required to treat heart attack less essential than drugs that fall in the "Essential Drugs List"? Are we suggesting that heart attack occurs only in rich patients?

- The cost of amifostine (used in ovarian cancer) is Rs. 4,500 per vial and the dose is 2 vials per day!

- The cost of triptorelin (for prostate cancer) is Rs. 6,500 per vial. Dose: one vial per 28 days till the unfortunate sufferer lives.

- The cost of paclitaxel (for breast cancer) therapy is Rs. 11,000 every week.

Selective profit control based on total volume, market share etc is not the answer to patients' problems. It may have an economic base but lacks scientific reasoning. A more humane and more scientific approach is required.

An overall profitability ceiling is required in a country like India because manufacturers routinely migrate from DPCO-controlled to non-controlled drugs. Recent example of a cough and cold remedy illustrates this point: Ten tablets of Cetrizet-D, a cough and cold cocktail marketed by Sun Pharma were priced at Rs. 8.11 in September 2003 but in less than a year the MRP was hiked to Rs. 28.20. How does this happen? Simple. Cetrizet-D initially contained cetirizine and pseudoephedrine. Once the "reasonably priced" product got established, the price-controlled ingredient pseudoephedrine was quietly replaced with phenylephrine which is outside the price control and price jacked up by 350! No one is informed that the new batch of Cetrizet-D is entirely different from the old batch, that one of the key ingredients has been changed which can pose dangers to patients apart from depriving them of their hard earned money. Doctors continue to prescribe and patients continue to consume the new Cetrizet-D under the illusion that it contains pseudoephedrine. Incidentally, the cost of producing 10 tablets of "new" Cetrizet-D is no more than Rs. 4.50 per strip of 10 tablets based on 5mg of cetrizine (Rs. 1725 per kg) and 20mg of phenylephrine (Rs. 10,750 per kg) plus tableting, stripping, printing and packaging cost of Rs. 1.40 per strip. Even if a liberal 100 per cent mark up is added for trade discounts and profits, the Maximum Retail Price (MRP) must not exceed Rs. 9. Actually the production cost of "New" Cetrizet-D is a bit lower than "old" Cetrizet-D, yet the company is charging 350 per cent more.

Due to lack of enforceable legislation on the lines of US Anti-Trust law, there is large scale price fixation. Example: the first batch of one brand of sildenafil 50mg was priced at Rs. 12 per tablet. Within a week another brand was launched with a price tag of Rs. 18 per tablet; the first brand quickly hiked the price in the very second batch! All the five subsequent brands are today equally priced at Rs. 18. If the companies were in the United States, there is every probability that all concerned CEOs will be behind bars!

Industry's New "Innovative" Arguments

Recently noticing that popular and political wind is blowing for increasing, rather than, reducing the span of drug regulation, the industry has come up with some "innovative" arguments. Let us examine their validity.

Argument No. 1: If drug prices are controlled, there will be no money to fund future research in discovering new medicines.

***Response*:** Do companies expect poor patients of India to pay them artificially-hiked prices of existing medicines (discovered abroad for which the companies have not paid a single paisa) so that in their sole discretion, they may spend money on R&D (a risky affair) ostensibly to discover new medicines and if at all they succeed, then sell them at their self-determined prices? This would mean that their toasts are buttered on both sides! Indian pharma companies are sitting tight over huge reserves. Let them put this money into R&D.

All over the world companies, not in just pharma but in all fields, first put in their own funds into research and then if successful they sell their products at a premium to recoup developmental costs.

If conceptually this line of industry's argument is accepted then why restrict it to pharma sector? Why not allow telephone instrument manufacturers to jack up the prices, so that the excessive profits can be ploughed back into telecom research? The only and correct way to encourage R&D is for the government to give suitable incentives (for example, total excise relief, for say five years, if the company produces a commercially successful novel product), income tax rebates (already available) etc. and provide infrastructure at reasonable cost. To ask poor patients to pay for R&D in advance in the commercial interest of companies is strange and selfish to say the least.

In any case, as of date R&D is merely a convenient argument to keep the profits high. The cost of discovering a new drug up to commercial exploitation in the West is Rs. 3,700 crores – and this money has to be spent by one company and not all of them put together. Assuming that Indian cost is just 700 crores (based on purchasing power parity of Indian currency at 5.29 times that of US dollar), no Indian company spends even one-third of this amount on R&D. In fact last year (2003-2004), all Indian companies put together spent 660 crores on R&D, not to mention the fact that many non-R&D expenses are routinely booked under this heading to save on taxes. As of date, R&D is merely a slogan: Not one successful new medicine has come out of India in the last three decades!

Argument No. 2: All price control efforts land in litigation and there is already a big backlog. Besides National Pharmaceutical Pricing Authority (NPPA) has a small staff and the task is too big.

***Response**:* Does it mean that people should suffer and pay through their nose because of administrative or legal failure? It is no secret that many defective orders are deliberately issued with large loopholes so that companies can get around the law.

Argument No. 3: Pharma companies cannot export at a price more than what they are selling within the country; therefore there will be national loss.

***Response*:** Of all the arguments given in favour of free-for-all price regimen, this is the most strange and self-serving.

Conceptually, the dynamics of export are entirely different from domestic marketing. There is adequate documentary evidence with the Customs Department to prove that:

Some drugs are being exported at half, if not less, the domestic prices.
Some drugs are being exported at nearly the same rate as domestic prices while
Some medicines are being exported at twice the domestic prices.

Also domestic prices of the same molecule vary a great deal; sometimes, more than 100 per cent (example: Amlodipine). Hence the argument is devoid of any merit. Examples:

Export at lower prices: Fracillin (ampicillin) 250mg exported at Rs. 6.05 (Freight On Board- FOB) while the domestic price is Rs. 22 (exclusive of excise and trade margins).
BQL (enalapril) exported at Rs. 11.37 (FOB) while the domestic price is Rs. 22 (exclusive of excise and trade margins).
Ampicloxacillin – 250/250 exported at Rs. 11.48 (FOB) while the domestic price is Rs. 20 (exclusive of excise and trade margins).

Export at equivalent prices: Zentel (albendazole) exported at Rs. 11.53 (FOB) while the domestic price is Rs. 10 (exclusive of excise and trade margins).
Calcigard (nifedipine) exported at Rs. 6.75 (FOB) while the domestic price is Rs. 6 (exclusive of excise and trade margins).

Export at higher prices: Jocet (cetirizine) exported at Rs. 35.77 (FOB) while the domestic price is Rs. 13.94 (exclusive of excise and trade margins).

Besides, there is no monolithic "Indian Pharma Industry" acting in unison. Various companies are in fierce competition with each other and undercutting each other abroad. For example, Herpex (acyclovir) brand was exported to Lusaka at Rs. 36.49 but it was undercut by Vivorax brand at Rs. 20.37. Similarly Stamlo (amlodipine 5mg) was exported to Male at Rs. 2.21 but undercut by Amlodac at half the price – Rs. 1.12.

Therefore, domestic retail prices are not and can never be the basis or yard stick for export policies and prices. They are based on actual costing and opportunities available abroad. Besides, more than half of exporters do not have domestic retail sales (such as Divi's, Matrix etc.) and hence they are not concerned with domestic prices. Similarly, every Indian company retailing at home is not involved in exports. Assuming that the argument was conceptually valid, why should non-exporters get undue benefit at the cost of poor patients?

As per Pharmexcil data, total pharma exports in 2003-2004 were around Rs. 14,000 crores. Out of which about 60 per cent (approximately 8,500 crores) are bulk drugs and intermediaries. Consumers in India are not affected adversely by export pricing of bulk drugs. The export of finished medicines (ready-to-consume) is about Rs. 5,500 crores out of which regulated markets (Western advanced countries) account for about 30 per cent (Rs. 1600 crores) and balance (Rs. 4,000 crores) goes to unregulated markets in developing countries.

Domestic formulation prices have nothing to do with exports to advanced Western regulated markets because extensive and stringent rules of quality and manufacturing facilities apply requiring pre-approval inspections severely limiting the number of competing exporters. No one in USA expects to get 10 tablets of Ranitidine 150mg for Rs. 4 (US 10 cents) when the domestic price in USA is US$ 5.

Domestic marketing is 'doctor-and-chemist centric' since consumers (patients) do not decide which, in what quantity and when to buy medicines. The entire thurst is to 'convince' prescribers and retailers. On the other hand exports are 'buyer-centric.' an importer or actual user in Vietnam, will only buy medicines from Indian exporters if the price suits he will shop around the world to find the lowest price. The importer in Vietnam will not look at Indian domestic prices. If the buyer, irrespective of domestic prices in India, finds a cheaper source he is not going to oblige companies in India.

Even otherwise domestic prices cannot be pegged simply to help exports. If this concept is accepted then all prices, such as tea, bicycles, iron should be hiked so that exporters in India can sell their merchandise abroad! Asking poor patients of India to pay higher prices for medicines so that companies make excessive profits twice – local sales and export earnings – is a unique, never-heard of argument in the past.

Argument No. 4: Why control only medicine prices when everything else in health care services is not controlled?

Reply: It is a skewed argument. The solution is to regulate all healthcare costs by increasing (like England) the resources for state medical care rather than throwing poor people at the mercy of private profit-making institutions. It is shameful that on the one hand Planning Commission admits that over 35% of people in India live below poverty line and on the other hand 80% of all people depend on extremely expensive, unaffordable private sector for their health needs.

Argument No. 5: Drugs are only a small part of health care expenses. So why are you focusing on this?

Response: Drugs are not that small a part as it is made out to be. They constitute over 40% of cost of treatment – the single largest component. The sum of 18,000 crores of medicines being sold by the organised sector in the domestic market is a huge amount. The answer is to regulate all healthcare costs including drug prices.

Price Regulation: Some Suggestions

The objective of the drug price regulation is that people should get quality drugs at fair prices. Therefore, in addition to regulating prices of all medicines of a particular therapeutic category, the following measures are recommended:

All tablets/capsules and other oral solid formulations of 10 units of which the Maximum Retail Price (MRP) is Rs. 10 or less should be outside the price control. (Explanation: Rs. 10 MRP means approximately Rs. 7 realization by manufacturers since balance of Rs. 3 goes to transportation, retail margins, excise duty etc.). Similarly all liquid products below Rs. 15 need not be price controlled. These two steps will eliminate a huge number of formulations from the process of price control. One can have a similar cut off point for ampoules/vials.

All equivalent formulations where the difference of MRP is more than 25% between the lowest and highest MRP will be monitored and brought under DPCO if necessary (Review is required so that predatory pricing to kill pharmacological or therapeutic category competition is not resorted to). DPCO should encourage manufacture of quality formulations. MRP of only those formulations will be considered as base price that are manufactured at factories that comply with Schedule M that specifies the minimum standards. In addition manufacturers whose formulations are produced at WHO/European Union (EU) certified or USFDA-approved premises will enjoy a further mark up of 10 and 20 per cent respectively.

The policy on overall profitability ceiling as stipulated in DPCO should be implemented but to be restricted to domestic business only, so that export profits are not regulated.

All Fixed-Dose Combinations (FDCs), introduced after May 1, 2002 without DCGI marketing approval should come under DPCO (On 1-5-2002, D&C rules were amended to make it obligatory for companies to seek prior DCGI approval before marketing any FDC). Since state controllers continue to issue manufacturing licenses indiscriminately in violation of law in connivance with unethical manufacturers, a way has to be found to discipline such companies. FDCs marketed without DCGI approval will not be entitled to relief as suggested under Point 1.

June 30, 2004

Chapter 4: Pharma Pricing in India: a failure of the Market(s)?

> *"People of the same trade seldom meet together even for merriment and diversion, but the conversation ends in a conspiracy against the public or some contrivance to raise prices." –Adam Smith*

The markets are supposed to have the wisdom[1]. The usage of the word 'market' and its supposed wisdom harks back to atleast Adam Smith who advocated the invisible hand (actually only once, in passing, in his *Wealth of Nations*) that somehow brings equilibrium to supply and demand and therefore prices. More recent and sophisticated defendants of the market have included Hayek who had this to say in his Nobel Lecture, *Pretence of Knowledge:*

> It is indeed the source of the superiority of the market order, and the reason why, when it is not suppressed by the powers of government, it regularly displaces other types of order, that in the resulting allocation of resources more of the knowledge of particular facts will be utilized which exists only dispersed among uncounted persons, than any one person can possess. But because we, the observing scientists, can thus never know all the determinants of such an order, and in consequence also cannot know at which particular structure of prices and wages demand would everywhere equal supply, we also cannot measure the deviations from that order; nor can we statistically test our theory that it is the deviations from that "equilibrium" system of prices and wages which make it impossible to sell some of the products and services at the prices at which they are offered[2].

Let us assume for the time being that the market(s) indeed has/have wisdom. Do stock markets for instance have wisdom? Wisdom for what you may ask. This wisdom is usually related to its calculation of what stocks, and what companies, are profitable. Now no ethical criteria or criteria for long-term ecological and/or civilizational sustainability enter into it. Otherwise Union Carbide and Coca Cola should have been consigned to the dustbin of history.

Even black-markets (those arbitrarily defined sites of economic crimes) have wisdom. Wisdom to know where the goddess Lakshmi smiles. She seems to smile on the rich and crooked more, much lesson on your meek and innocents and your huddled masses.

Markets are supposed to be allocatively and productively efficient. But the efficiency criterion eschews what economists conveniently call externalities. A market can end up catering to a minority of population. That is a major segment of the population can be priced out of the market. Or never even considered as target segment for consumption. What does it matter to the producers of goods (say medicines) if a lot of people die a slow death because of poor or no access to medicines as long as the firm is making profits and the stock prices are doing well (wisdom of the markets)?

If the same good is available at comparable quality, at a range of prices, is the market allocatively efficient? If more players do not automatically reduce prices, or if the most selling brand also sells at the highest prices, is the market efficient? Obviously no. But that is the situation of the pharmaceutical market today in India. It is neither productively nor allocatively efficient. But the shares in the markets are doing well.

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[1] The term 'Markets' is currently being used as a synonym for the stock market. But we use it in the generic sense: the market as in the free market worldview in general.

[2] Of course Hayek's defense of free market and what he called decentralized market socialism was far more nuanced than the above quote suggests.

Competition felt Adam Smith and many after him should reduce prices. What is competition? To an economist it means:

1.Existence of very large number of buyers and sellers, each consuming and producing a small fraction of the goods in the market.

2. The producers and consumers are such a small fraction of the market that whether they buy or sell, it has no influence over supply and demand.

3.All the items in the market must be identical.

4. There can be no substantial barriers (obstacles) to entry into, or exit from, the market.

All these above exist, for the pharmaceutical sector in India. Still we have a situation where prices defy competition. With the help of branding, and sometimes without branding, pharma companies tend to resort to product differentiation. That is their aspirin is somehow better than the other aspirin. Adequate competition, and certainly, perfect competition, does not, apparently, exist in the Indian pharma market.

In economic literature, market failure is said to occur when inter alia:

1) When adequate competition does not exist.
2) Buyers and sellers are not well informed. Without information uneducated decisions are made.
3) Resources are not free to move from one industry to another (resource immobility)
4) Prices do not reasonably reflect the costs of production.
5) Presence of

- Negative externality- harmful side effect that affects an uninvolved third party. In most events, it constitutes external cost. In this case, production of irrational and unscientific medicines. Or 20-year long patents restricting entry of other players. Or use of unethical marketing techniques.

- Positive externality- beneficial side effect that affects an uninvolved third party.

6) Production of public goods (supplementation by the government or subsidy).

We argue conditions 1, 2, 4 and 5 definitely hold for the pharma formulations sector in India.

Evidence from India's Pharma Industry

Competition does not work in the Indian pharma industry - always. More players in an uncontrolled market have meant only a wide range of prices for the same drugs.[3] On the other hand, you have the same drug being sold by different companies (and sometimes by the same company) at vastly different prices. (See Tables 2-7 and related discussion in Chapter 1; and Chapter 2 for the Anarchy in Retail Drug Pricing in India). There is not even a direct relation between top-selling drugs and real need as per the disease and illness conditions prevalent.

Secondly, the most-selling brand is seldom the lowest priced. The product leader is often the price leader too. (See Table 2, Chapter 1 and related discussion.). If some semblance of competition existed it would have been otherwise. If one would insist marginal revenue is equal to marginal cost – the criteria for perfect competition -- for the pharma company rolling in billions, it is laughable.

[3] See the article 'Drug Price Control: Principles, Problems and Prospects' by Chandra Gulhati, Chapter 3 of this book.

Thirdly, retail market prices are often 1-3 percent of government tender prices. This shows if anything the tremendous overpricing without precedent -- in times of relative peace – in any other industry in the world (see Table 3, Chapter 1). Also this percentage differential in pricing for the public sector and private retail sector is probably true of no other industry in India – or in the world. Would the booming computer industry sell in the market a laptop at Rs 100,000 and to the government tender for Rs 2000 to Rs 3000/-? Would a truck manufacturer sell trucks for Rs 5 lakhs in the market and to the government tender for Rs 10,000/- to Rs 20,000/- even if he had an order of 10,000 trucks at a time? This however is the situation of the drug industry in India.

Market Fundamentalism

…Welcome to the World of Market Fundamentalism. To the Final Solution.

Flip channels on television and you can't miss it. Gaggles of elegantly clad and very earnest young men and women speaking breathlessly about The Market (you can hear the capital letters). And of course, the need to 'unleash' its creative energies. It's not only these young who hold this view, though. Several older people do, too. But perhaps they're somewhat tainted, having romanced other gods in the past. This does not, however, induce much modesty in the line up of editor-analysts we're condemned to hearing forever on the theme.

There is no miracle the market cannot perform. Market forces, as Swaminathan Aiyer argued long ago, are great for the environment. Markets are green. We've learned more since then. *Time* magazine's Charles Krauthammer has laid down that while better-off workers are abandoning the less fortunate ones, the market is rescuing the 'once colonized'. It is in fact the lifeline for 'previously starving Third World peasants.'

Markets are also perfect for the field of public health. So perfect that hundreds of elderly American citizens get some exercise each year as a result. The incredible cost of drugs in their country compels them to drive all the way to Canada to buy medicines there. (But wait a minute, that's a distortion of market...).

The market is not merely inseparable from democracy. It *is* democracy…

…Hunger is a function of anti-market systems. Want more jobs? Free the market. Crisis, whether in education or agriculture, is best dealt with by not dealing with it at all. Leave it to the market. Let the market decide. Some analysts now even see an intrinsically anti-caste character in the market.

Welcome to the world of Market Fundamentalism. Reaganomics and Thatcherism fought many crusades for the new religion in the 1980s. India in 1991, along with many others, embraced that world with much enthusiasm.

Source: P.Sainath, 'And then there was the Market', *Seminar*, Jan 2001

Pharma Scenario under Market Failure

Considering the evidence referred to above briefly, and presented in more detail in the other chapters of this book, the Indian pharma scenario, as far as the consumer is concerned, is a failure of the market. As a result of this extreme market failure and failure of regulation in the absence of well-functioning markets, the drug (medicines) availability situation in India is one of poverty amidst adequacy – there is poverty of supply of even essential drugs to the poor despite adequate drug production.. Also the following features obtain in the Indian pharma sector – evidence of extreme market distortions, of profit maximization without bothering about short-term and long-term consequences on people:

1. A significant percentage of drug formulations are irrational. Some are even therapeutically useless, unscientific and hazardous. Irrational combinations rule the roost. The market is flooded with numerous potency drugs, aphrodisiacs, antibiotic combinations, multi-ingredient analgesic combinations, digestive enzymes, cough syrups, and tonics and vitamins of little or doubtful therapeutic value. Ironically, many of these irrational drugs are amongst the top selling drugs. Vitamins and tonics, and other unnecessary and often inappropriate, ineffective and costly nutritional supplements, dominate in terms of sales[4].

2. Drugs banned in several Western countries, and otherwise considered unscientific and/or hazardous, continue to be produced in India.

3. Prescriptions are influenced by aggressive promotion of drug companies. As a result, the patient often does not get the most scientific prescription leading to over/under prescribing[5].

4. This is compounded by inaccurate diagnosis, lack of up-to-date knowledge, unethical practices like receiving commissions for prescribing certain drugs and sponsorship by drug companies of individual doctor's expenses as well as of medical conferences, etc.

5. One upshot is demand is supplier induced. The health market creates and promotes wants. Doctors also set themselves as gate-keepers, with societal sanction, to certify various physical states of being including starvation[6], birth and death.

6. Companies often fail to provide consumers with unbiased information about the drugs they sell. The labels on drug packages frequently omit to mention the mandatory warnings and cautions. Similarly, drugs not recommended for the elderly, for children, for people with liver or kidney impairment do not carry appropriate warnings. Ironically, when these warnings *are* present, the size of the print used to describe the 'contradictions', 'side-effects' or even 'the ingredients' is so small that they can hardly be seen except with a magnifying glass. Only the brand name is well displayed.

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[4] See 'Marketing of medicines in India: Informing, inducing or influencing?' by Dr. Chandra Gulhati, BMJ 2004; 328:778-779 (3 April). See also for instance: Pharmaceuticals: Restrictions in Use and Availability (WHO/EDM, 2001); Guide to good prescribing: A practical manual (WHO/EDM, 1994); WHO Policy Perspectives on Medicines 2002, June:The Selection of Essential Medicines (WHO/EDM, 2002); The Use of Essential Drugs: Ninth Report of the WHO Expert Committee (WHO/EDM, 2000). See also for analyses of Indian situation prevailing:

a) Desai, S.V. 1990. 'Anaemia and Oral Haematinic Preparations'. *Drug Disease Doctor*; Vol. 3, No.2.
b) b) . Desai, S.V. and R.S. Desai. 1991. 'Rational Cough Mixtures: Analysis of Proprietary Preparations'. *Bulletin of Society for Rational Therapy*, Vol. 3, No. 5.
c) Modak, Shishir. 1984. *Rationality Analysis of Anti-diarrhoeal Preparations*. Medico-Friend Circle, Pune.
d) Phadke, Anant. 1985 'Scientific Scrutiny of Over the Counter Drugs'. *Medical Service*, Octo-Nov, pp. 30-42.
e) Phadke, Anant and Deepak Deshpande. 1992. 'A Review of Haematinics Marketed in India'. *Drug Disease Doctor*. No. 28, pp. 88-92.
f) Rane, Wishwas. 1994. 'Ayurvedic Drug Formulations: Are They Rational?' Paper Presented at the IOCU-ACASH Workshop on Consumer Education, Drugs and Media, April 3-4, Bombay, p.5.
g) Uhrig, Jamie and Penny Dawson. 1985. *A Rationality Study of Analgesics and Antipyretics.* Medico-Friend Circle, Pune.
h)

[5] *Surviving the Pharmaceutical Jungle* by Nobhojit Roy and Neha Madhiwalla is a new WHO funded study on the unethical promotional practices of pharma companies in India. See also the Jan-Mar 2004 of *Issues in Medical Ethics.* For the study see www.issuesinmedicalethics.org/docs/Pharmrpt.pdf

[6] Thanks to Sunil Kaul, Bongaigon for pointing this out.

7. Although in 1996, the Health Ministry came up with a list of essential drugs, the Chemicals Ministry, which is the nodal ministry for making policies relating to drugs, has not included any clause in the current drug policy (Pharmaceutical Policy 2002[7]) to ensure that a certain percentage of all drug production is used for the production of essential drugs. A National Essential Medicines List (NEML, 2003) has been brought out by the Government of India, presumably as the basket from which to apply criteria that will keep drugs in price control[8].

8. Poor infrastructure for quality control, weak-kneed and poorly staffed regulatory administration and overpricing of several drugs are the rule rather than the exception. The Drug Technical Advisory Board (DTAB), the body whose duty is to opine on the rationality of drugs in India, does not meet as often as it should to advise the government on rationalising the drugs in the market.[9]

Pricing and Related Matters

9. Drugs (pharmaceuticals) are overpriced as already pointed out.

10. In no country with a world-class pharma industry does the drug administration allow at the same time essential drugs and irrational and non-essential drugs.

11. Most of the lifesaving drugs like that for AIDS/HIV, TB, malaria, cancer, heart conditions are not in price control and are extremely highly priced.

12. The Indian drug scenario of anti-poor pricing is compounded by poor regulation of the medical profession, of the retail pharmacists, of the pharmacy profession, and poor drug control.

13. Also of a serious nature is the lack of serious prosecution of offenders as well as the will to prosecute those selling substandard, sub therapeutic and spurious drugs.

14. The end costs of drug therapy become even more unaffordable because of prevalence of many irrational, unscientific and harmful drugs as also leading to "therapeutic chaos and therapeutic nihilism" in the Indian market and among medical professionals.

15. The serious implications for people's health and therefore national security due to ignoring the public health scenario in the formulation of the pricing and pharmaceutical policy is reiterated with fresh data..

16. Equally alarming in terms of effects on the consumer is the burgeoning field of nutraceuticals –nutrient products positioned by drug companies as therapeutically advantageous. These are extremely overpriced apart from promoting a want and not a need.

Box 1

Guidelines for Rational Use of Drugs

- Prescribing a drug only when genuinely indicated
- Choosing drugs which are effective
- Using single ingredient drugs
- Using drugs indicated for specific conditions
- Choosing drugs which are relatively safe
- Choosing cheaper alternatives.

Steps to rationalize the use of drugs in the market:

* Elimination of new drugs which are expensive and not necessary because other drugs with proven efficacy already exist in the market.
* Elimination of useless, hazardous and harmful drugs which have irrational combinations
* Use of essential drugs list
*Marketing of drugs by their generic name

Source: *A Lay Person's Guide to Medicine. What is behind them and how to use them*. LOCOST, Baroda, 2000

[7] For Pharmaceutical Policy 2002 and previous drug price control policies see http://www.nppaindia.nic.in/index1.html

[8] For National Essential Medicines List (NEML) 2003 see http://www.expresspharmapulse.com/nedl.pdf

[9] The failure of the the Drug Controller of India to make public the brand list of the formulations banned, the reasons thereof and the alternatives available, continues to be a major block in spite of Supreme Court directions. For instance, very few doctors and chemists are aware that B1, B6, B12, have been permitted only for acute peripheral neuritis; analgin for severe pain only when not responding to other pain killers; and that oxyphenbutazone and phenylbutazone is permitted only for acute ankylosing spondylitis or acute gouty arthritis. Most doctors and consumers are not aware of these restrictions, as DTAB decisions have not been communicated to them.

Asymmetry of Information

Referring to the pharma market, a doctor friend of the writer said: "In no other situation in life does a consumer buy goods of which he/she has no knowledge, buys on the written recommendation of a second party from a third party; and the second party may charge heavily for doing so; and the second party may also get paid by third party and other parties manufacturing those goods; and bought usually at a time of severe distress with death as a possible threat of non-purchase. Is this not, combined with the above irrationalities, sufficient cause for thorough overhaul of the drug control and pricing system of India?"

The doctor friend is referring to extreme asymmetry analysed by Akerlof et al. In the instant case, the consumer may not get lemons most of the time, but tends to do so for a significant part of the time, and in the absence of regulation of the drug industry and of medical practice, lemons are what a poor person gets on the whole. Lemons in the skin of alphonso mangoes.

There is a difference though with Akerlof who tried to show for instance that 'the market for used cars--because of asymmetric information--is likely to be quite a small market and that other markets with sufficient asymmetric information will, in fact, collapse and will not be there at all. The leading and most obvious such failure is in health care insurance.' In the case of the pharma sector in India, the market exists, it is anything but small, may be even flourishing, but as a paradigm of meeting health care requirements efficiently in the long run, it appears to be a failure. This prevalence of chaos is seen as an argument for health insurance, not necessarily State-guaranteed universal health insurance, with every danger that health insurance premia would be priced out of the reach of the poor.

The effects of this extreme asymmetry need regulation from the government and intervention from a whole lot of other external actors, if justice is to be done and the patient has to be fully cured.

Asymmetry and Rational Choice

Again, it is this asymmetry of information that precludes the possibility of rational (reasoned) action. Rationality in the larger sense as well as in the limited sense used in rational choice theory. In the literature of the latter, human beings are essentially seen as utilitarian, all human action a result of deliberate, calculative strategies, calculating the costs and benefits of alternative courses of action, and talking of getting 'value' for money ("paisa vasool"). This has been now sufficiently shown to be absurd (including famously by Amartya Sen in his description of Rational Fools) in the context of having to explain things like committent, altruism and ideologically motivated behaviour. Of course it is possible to see asymmetry and lack of information themselves as another set of constraints to be factored into before engaging in motivated, rational behaviour. However, at best this is a trivial way of making the theory inclusive and all explaining.

But let us look through the lens of rational choice behaviour in the pharma industry and patient-doctor behaviour. Are doctors rational in choice of treatment and prescriptions? Yes, your average doctor tends to be rational in the sense that he/she would do even irrational (= unscientific) things to maximize self-interest –prescribing unnecessary tests and/or drugs for instance. Also however guiding his/her behaviour is some need for self-preservation as a guild, as well as, at least in some cases, adherence to ideology (in this case the ideology of reason as embodied in the best of medical science.). The medical profession, especially when it is poorly regulated as in India, seems to be a case of rational behaviour in the economic sense with few willing to subsume Reason (as in scientific logic) in the larger sense to the altar of market forces and commerce. However few in the medical profession, maybe only those at the edge of ethical behavior, truly are calculating in terms of costs and benefits before every action. Recall the popular perception that American doctors always take time and explain where as your average Indian doctor does not do so –the difference is explained by saying American doctors have malpractice suits hanging over them. Rationally calculated behaviour or true concern for the patient? Difficult to say.

Do drug companies indulge in rational choice? Indeed they would appear to be. They do seem to be interested in maximizing profit even at the risk of making unnecessary drugs, at the risk of sacrificing scientific behaviour in the

larger sense of promoting irrational therapy[10]. However even here there is some measure of self-preservation in their apparent subservience to the rule of law. A socially responsible corporate at best is seen as an oxymoron, as socially responsible behaviour in many cases of corporations and certainly of drug companies seems to be motivated by self-interest and 'winning' in the market. A drug company seems nearest to the economic paradigm of 'rational' behaviour.

What of the patient? Does he/she indulge in rational/irrational behaviour? This is very difficult to say. The health seeking behaviour and motivations are often guided by self-preservation and that is understandable. But how do I make choices of which physician, which therapy, which drug – whether to take a drug or not or whether to continue with a therapy or not? Here there is a tremendous asymmetry of information. Few patients, if at all, have information that can be understood by them for making decisions about therapy, drug regimens and choice of doctors and treatment facilities. One goes at best by popular perceptions and socially shared evaluations. Much of patient behaviour in the absence of information is irrational and that on the top of irrational, unscientific professional advice proffered doubly so.

A related issue where asymmetry is a real issue is when ordinary patients are selected for clinical trials (say for a trial of an experimental drug) or a trial of a new experimental therapy – theoretically informed consent is taken but how many patients - -and in India these are in many cases illiterate – understand what they are getting into[11].

What of governments' rational behaviour with respect to health? Here again it is clear (to some of us) that a government by spending less on health services and doing precious little or not applying its mind is palpably indulging in irrational behaviour of economic and non-economic kinds.

Amartya Sen in his *Rationality and Freedom* defines Rationality "as the discipline of subjecting one's choices—of actions as well as of objectives, values and priorities—to reasoned scrutiny. Rather than defining rationality in terms of some formulaic conditions that have been proposed in the literature (such as satisfying some prespecified axioms of 'internal consistency of choice,' or being in conformity with 'intelligent pursuit of self-interest,' or being some variant of maximizing behavior), rationality is seen … in much more general terms as the need to subject one's choices to the demands of reason.''

If one takes this more acceptable definition of rationality, the behaviour of most of the actors in the health care scenario of India –drug industry, doctors, and policy makers – are not strictly rational. That is at best their behaviour would exhibit a mix of science and commerce: rationality in the pure economic sense with appropriate rationality in the scientific sense. The latter too, if you would want to be even more cynical, is because of calculations of economic rationality. Patients are forced to be irrational or adopt irrational behaviours by default and lack of choice. The only choice they have is not to approach an irrational doctor but they do not know he/she is one such apriori.

Differential/Tiered Pricing, Ramsey Pricing

In order to obviate the charge of overpricing, pharma lobbies in industry and academia internationally have advocated differential or tiered pricing. Differential or tiered pricing for medicines means basically pricing for different types of markets, that is, a lower price in the poorer countries and a higher price in the richer nations, has

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[10] "…Companies find it hard to generate prescriptions based solely on science. Relying on published datasheets issued by the inventing companies reduces the scope of a drug because of the inconvenience of contraindications, precautions, drug interactions, and adverse effects. Sometimes, for purely promotional purposes local data are generated, as happened with letrozole, which was given to over 430 young women to test its efficacy in inducing ovulation. Without new molecules, companies create "novel" products by mixing two or more medicines in a fixed dose combination. Such combinations are often irrational, and some pose danger. Short term use of combinations of quinolones with imidazoles for undiagnosed diarrhoea is encouraging *Salmonella typhi* resistance to quinolones**…"** **(**Chandra Gulhati in 'Marketing of medicines in India: Informing, inducing or influencing?' in *BMJ* 2004; 328:778-779 (3 April),

[11] See for instance 'Drug trials and questions', *Frontline*, Sep 14-27, 2002, regarding the controversy surrounding Danish pharmaceutical multinational Novo Nordisk's phase 3 trials of ragaglitazar (NN622/DRF-2725), a dual-action insulin sensitiser.

been advocated by those who are keen to end the mounting criticism and embarrassment of the of big pharma corporations and their perceived profiteering. This has some kind of theoretical support in economics literature – the so-called Ramsey Pricing.

Ramsey pricing in its original form meant charging a higher price, the less elastic the buyer's demand - the less elastic demanders paying more and the more elastic demanders paying less. (Price elasticity of demand is defined as the percentage change in quantity in response to a percentage change in price. If a market demand is sensitive to changes in prices, then the demand is elastic. If nobody could care what price a drug is priced and are still willing to pay for it, the market is inelastic.) In theory, and at first glance it looks attractive, but basically it turns out that it justifies monopolies and/or high pricing by big companies. By offering to settle for lower prices in poorer markets (who decides the lower prices would still be affordable to the poor?), the big company effectively shuts off competition and innovation, from smaller generic producers for instance –an eventuality likely to be assured by the onset of tighter intellectual property rent collection devices like the TRIPS and WTO. This in Ramsey pricing literature is considered economically efficient pricing – as the big pharma company can have its cake and eat it too – they can indulge in monopoly behaviour and monopoly pricing, ensure their so called R&D costs are recouped, and yet get by feeling that they are after all not so heartless with regard to the poor. Defendants of differential pricing have argued that Ramsey pricing ensures rewards on innovation by the corporation.

But is it really free trade/free market/perfect competition when you have practically made your market captive to your product (for 20 years in the case of a new drug in the post-product patent India of 2005 and after)? Monopolies with constant rent-seeking (that is patent protection) through newer uses of a drug or newer presentations of a drug are in the long-run –some even in the medium run – are as much as a paradigm of inefficiency as any protected market. Whither perfect competition?

A related question is who or what is free in the 'free market'? Does it imply freedom of some kind? Who then has the freedom –buyer, trader, manufacturer? When, what I consume and at prices is dictated by forces beyond my control, do I enjoy freedom of choice?[12]

Pretence of Certainty?

Much of what we have observed about the economy-related features of the pharma sector hold true of the health sector in India and elsewhere in the world. More germanely, why do policy makers, pharma industry lobbyists and other motivated commentators pretend that the usual rules of economics work in the pharma and health sector: namely of competition driving down prices given especially the asymmetries of information involved. That competition, or what goes in its name, in a deregulated market has allocative and productive efficiency?

Why then do policy makers pretend that the free market will take care of the challenges of health care – of providing accessible and affordable health services and medicines? It is not as if mainstream economics has held steadfast to free market and perfect competition – in fact the work of Akerlof and Nash, Harsanyi and a host of game theorists among many others try to address precisely how economies and markets work in their departures from the idea of perfect competition and complete information.[13]

The idea of free market and the associated virtues have not been realized in the health sector. Neither in this country nor in the so-called predominantly market economy countries has it worked, for the poor; and has certainly not demonstrated the virtues of allocative efficiency claimed, let alone promoting equity. Active and ongoing state-led intervention and regulation is the rule rather than the exception in almost all the so-called predominantly market

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[12] See Garlikov who deals this question at greater length in his essay on freedom in *Ethical and Philosophical Foundations of Economics* at http://www.garlikov.com/EPFE/chap24.htm

[13] There is a good case for describing the normal health seeking behaviour in India as a many person game with incomplete information and with players trying to maximize utility under incomplete information conditions. Mainstream economics in as much as it addresses the departures from free market, it is always as if it were an aberration that needs to be corrected.

economy countries, that is in countries where the free market philosophy is the dominant economic paradigm and is considered a given. While on the other hand there is no great evidence to conclude in general that State-sponsored regulation and or intervention is more effective and efficient in general, it can certainly be argued that State-sponsored or State-led regulation is certainly more responsive to the real health needs of people, like it or not thanks to vote bank politics[14]. And why not regulation in health services and the pharma sector given that we have some of regulation in telecom (TRAI for instance), insurance (IREDA), and the stock market (SEBI)? Drugs are equally if not more crucial for the common person. Why then this pretence of certainty that free market and competition work in the health sector? Pretence of Certainty of a consummation devoutly to be wished, if not prescient Knowledge of an eventuality foretold?[15] If the free market did not exist, it would be invented and along with it a suitable history and mythology.

The Common Minimum Programme (CMP) of the new government says, inter alia, "the UPA Government will take all steps to ensure availability of life-savings drugs at reasonable prices. Special attention will be paid to the poorer sections in the matter of health care. The feasibility of reviving public sector units set up for the manufacture of critical bulk drugs will be re-examined so as to bring down and keep a check on prices of drugs."

In the absence of universal and free access to health services for the poor, there is no alternative but to sensibly regulate prices of drugs like in the so-called free market countries, taking into account availability of reasonable profit margins for drug companies. The case of free market in the pharma and health sectors seems to be one of poor empirical record.

[14] The drug distribution services of the Tamil Nadu Medical Services is a kind of positive market intervention by the State and one which no successive government would like to reverse for fear of public wrath. And if one factors in better access to medicines for the poor in one's definition of allocative efficiency, the TNMSC, other things notwithstanding, is a good candidate for an effective intervention, in which poor people benefit ('better off than before"). A similar argument can be made for its mid-day meal programme.

[15] With apologies to Hayek

Whose interests do we give priority to? Voters? Or 'The Market'?

…Behind the stock market is the larger notion of `The Market,' a much wider political concept. And the conflict between that and democracy is very real.

The Wall Street Journal knows this. "Democracy is perverse," it whined about the poll results on May 19. "Although it is natural for the U.S. to suggest that all countries should embrace democracy, the lesson from India is that Western countries cannot be dogmatic about elections."

"As India's election will testify, democracy is not always supportive of coherent economic policy and prosperity." (Read: the voters are too dumb to know what's good for them.) On countries not yet at India's level, the *Journal* has some advice. The West "should be more hesitant about promoting political competition... " For alas, that "could destroy the leadership" that pursues vital economic change.

Maybe the *Journal* worries about post-June Baghdad? An elected government that might grumble when Dick Cheney's cabal plunders Iraq's oil? The *Journal*'s dilemma is a classic one. Market fundamentalism *versus* mass democracy.

It's a dilemma that has our own market *jihadis* seeking martyrdom. They go a step ahead of the *Journal*. With them, it's death to the infidels. "In 2004," writes a leading editor, "no government that the markets see as hostile can survive." The rhetoric of the rabble "has to be tempered to provide for the sensitivities of Dalal Street."

"The markets have spoken," declared another top Indian newspaper. But God is a bit edgy. "The markets are jittery," explained one business editor on television. "We need to soothe their nerves." (Hush now, the markets are asleep. Don't start off something by speaking aloud).

So, did 400 million citizens and voters queue in blistering heat of 40-plus to soothe the fretful nerves of the market? Some of us thought they were asserting their sovereignty. To demand the reforms they really needed. And to pass judgment on the market-driven reforms governments have followed. So what happens when poll verdict clashes with market edict?

The Wall Street Journal's answer: Don't waste time on the electorate. "The lesson of the past week is that if India truly wants to become an economic power it has to pay heed to the global voters known as investors, in addition to its own voters at home." We can listen to our people, says the *Journal* (gee, thanks guys) so long as they vote the way the investors want them to.

Surely, this is a regression? For years, the *WSJ* and others have argued that not only are markets intrinsic to democracy, they are democracy…

There is no miracle The Market cannot perform…

…Hunger is a function of anti-market systems. Want more jobs? Free the market. The crisis in agriculture is best dealt with by not dealing with it at all. Leave it to the market. Given its all-knowing wisdom, maybe the `The Market' ought to go out and seek a popular mandate….

…. Meanwhile, the media assured us all these years that the Indian Left is irrelevant. Unless it can learn from China. (China's CEO is our CEO?) Yet, the same pundits tell us that a couple of sentences from the irrelevant Left was enough to trigger "Bloody Monday."

There you are. Revealed — the secret of how to make the markets dance up and down in a frenzy….

…Market-worship is not novel. But the insane primacy it now gets is relatively new. Among other things, it reflects the ever-growing corporate links of the media. Links that spur them to mislead the public for their own profit.

"Markets are all about sentiment and confidence," gushed one TV anchor. "We must give them the confidence that governments will listen, that their interests will be honoured."

Voters, too have sentiments. Often very anti-market ones. They too wish to have confidence that governments will honour their interests. Whose interests do we give priority to? Voters? Or `The Market'? The corporate media have given their response to that question. The new Government still has time to find its answer.

Source: 'McMedia & Market *jihad',* P.Sainath in *The Hindu*, June 1, 2004

CHAPTER 5

WHAT THEY COULD BE?
DRUG COSTS IN TREATMENT OF COMMON AND IMPORTANT ILLNESSES AND AFFORDABILITY OF TREATMENT COSTS

-Anurag Bhargava[1]

The pernicious effect of the lack of regulation of drug prices is reflected in the costs of treatment to the consumer. If we consider their effect on the large number of indians who live on less than a dollar a day, the effect quite simply is in making medicines inaccessible to those who suffer most from ill health owing to their poverty and are in dire need of them. The result is untreated and partially treated illness and as a consequence significant morbidity and even death. The question of access to affordable essential medicines is a rights issue.

This exercise of computation of drug costs has the following objectives:

- To show the costs of the drug treatment, and their magnitude in relation to the purchasing power of the people.
- To show the enormous variation in drug treatment costs, contributed by the price variation in branded drugs in the retail market, which should obviously be eliminated or minimized.
- To show the enormous reduction in drug treatment costs which would accrue if the price of drugs in the retail market were related in some rational way to their prices quoted in open transparent tender. That is there needs to be a ceiling on margins and prices of medicines sold in the retail market.

in this note the costs of treatment of certain common and important illnesses, both infectious and non-infectious, are computed using the drug prices mentioned according to the prices mentioned in the Current index of Medical Specialties (CIMS) issue of July 2003. CIMS is a regularly updated prescriber's handbook, which gives prices of leading brands of drugs available in the market.

The disease conditions mentioned are a mix of acute and chronic infectious and non-infectious diseases.
Streptococcal pharyngitis (sore throat)
Dysentery with dehydration.
Worm infestation.
Fungal infection of skin
Tuberculosis
Hypertension
Diabetes
Coronary artery disease
Epilepsy
Iron deficiency anemia.

[1] The author wishes to acknowledge with thanks the help of Dr Smita Khobragade and Dr Meenakshi Jambulkar in tabulating and research of data.

Drug costs of treatment of other problems, which are threatening the control of preexisting diseases, are also mentioned. These are drug-resistant falciparum malaria, and multidrug-resistant tuberculosis.

for other assumptions used in calculating costs of drug treatment see Annexure 2.

Conclusions

The analysis that follows leads us to the following conclusions:

1) Drug Costs in Terms of Wages (or person Days of Wage Labour) of Poor

The magnitude of drug costs represents a huge burden for the poor of india who fall sick.

The following table computes the upper level of drug costs, which the poor have to bear if they are provided rational treatment. in actuality the drug costs are even higher because in addition to these drugs prescribing doctors often add a lot of unnecessary vitamins, tonics, etc.

The relation of these costs to the average daily wage of Rs. 60 (in a State like Chhatisgarh) is compared and the number of days a person would have to work to afford these costs are mentioned.

Table 3: Drug Costs and person Days in Terms of Wage Labour

Problem	Upper level of drug costs	No. of person-days to be spent in earning the drug cost.
1. Streptococcal pharyngitis (sore throat)	Rs. 109.8	1.8
2. Bacillary dysentery	Rs. 84.2	1.4
3. Treatment of iron deficiency anemia for 6 months	Rs. 3744	62.4
4. Tuberculosis treatment for 6 months	Rs. 2616	43.6
5. Treatment of multi-drug resistant TB for 18 months	Rs. 44190	736
6. Hypertension treatment for 1 year	Rs. 1076.75	17.95
7. Diabetes mellitus with oral drugs like glicazide	Rs. 2073.2	34.5
8. Coronary artery disease	Rs. 12541.4	209
9. Prevention of Hepatitis A	Rs. 1856	30.9

in other words to afford only the drug costs of treatment if the prescriber were to prescribe the expensive brands in the market, a poor man would have to spend his entire income of –

- Nearly 2 days to afford drugs for a bacterial sore throat.
- One month to afford immunisation for Hepatitis A
- More than one month to buy an oral drug for diabetes for a year.
- Nearly one and a half months to afford cost of TB therapy.
- More than 2 years to afford therapy for multi-drug resistant TB.
- More than 2 months to afford the best selling iron preparation for iron deficiency anemia.
- More than half the year to afford costs of drugs for coronary artery disease.
- How can a man earning 60 rupees a day and barely meeting the daily needs of his
- family afford such therapy?

2) Reduction in Drug Costs in Treatment with Less Expensive Brands

Significant reduction in drug costs could occur if the least expensive preparation among the branded preparations were used in the treatment of various diseases.

There are marked differences in the prices of various preparations available in the market ranging from 115%-1108% for the same product.

From the data in Table 4 below it is clear that if the less expensive brands were chosen, then –

- in the therapy of infections nearly 50% to 100% reduction in treatment costs could occur.
- in the case of worm infestation a 10-fold reduction could occur.
- in the treatment of non-communicable diseases like anemia a more than 15-fold reduction of cost could occur.
- Even in conditions like coronary artery disease, hypertension, and diabetes, 2 fold to 5 fold reduction in costs is possible.

3) Drug Costs with 100 percent Margin over Tender Prices

If the drug prices in the retail market were a 100% markup over the tender price the results would be as mentioned in the tables, patients would have to pay:

- Less than half of the amount on treatment of tuberculosis.
- More than 2 fold less on treatment of most acute infections.
- 3 times to 9 times lesser on treatment of diabetes mellitus.
- More than 10 times lesser on treatment of hypertension.
- Less than 50 times what they have to spend on treatment of anemia.

4) Systemic Effects of Lower Price of Drugs

- The affordability of medicines would be far higher.
- Financial burden on patients would be far lower.
- Volume of sales would increase with more people coming forth to buy medicines owing to the reduction in prices.

5) Some Drug Cost-Related Concerns

a) Absence of Crucial Drugs from Price Control as well as National Disease Control

There are some diseases for which neither is there provision for drugs under the national programs, nor are the drugs covered under the Drug Price Control Order.

for instance, the drugs required for management of Multi-drug resistant TB which are at present way beyond the reach of the common man. The problem for which they are required is also huge. Although reliable estimates in this regard, india which has one third of the world's cases of TB, historically a poorly functioning program with low cure rates, would also have the world's largest number of patients with multi-drug resistant TB.

b) Exclusion of Vaccines

The exclusion of vaccines from the purview of the DPCO is also inexplicable, for there is now a proliferation of expensive vaccines offered to the public which are outside the present purview of the National Immunisation program viz. vaccines for hepatitis A, hepatitis B, typhoid, Hemophilus influenzae, vaccines for rabies. Given the public health importane of these diseases, the variation in prices of vaccines available, there is a strong case for including them in the purview of Drug Price control order.

6) High Price of Drugs is Violation of Human Rights

* Health is a fundamental human right and access to affordable essential medicines is a prerequisite to the realization of this human right. It is for the government to safeguard this right, which affects the right to life. The accessibility to and affordability of drugs is a rights issue.

* The wide variation in drug prices and profiteering which occurs in the name of operation of market forces impinges on the patient's right to life.

* If a patient with iron deficiency anemia has to pay almost 50 times for its drug treatment what he/she should have to pay, and if that preparation also happens to be the best selling one, it should be seen as an infringement of his human rights.

* Patients and their health and lives cannot be held hostage to market forces, which as shown will not operate to their benefit until this is ensured by the government.

Table 4: Costs of Drug Treatment for Common Illnesses[2]

Condition To Be Treated	Drug cost using most expensive brand	Drug cost using least expensive brand	Drug cost using 100% markup over TNMSC price.	Overpricing in percentage between brands	Overpricing in % between 100% markup over TNMSC rates and the expensive brands
I. Strepto-Coccal Pharyngitis	Rs. 109.8	Rs. 78	Rs. 36.6	139%	305%
II Bacillary Dysentery	Rs. 84.2	Rs. 60.3	Rs.21.48	139%	391 %
III. Fungal infection of Skin	Rs. 99.6	Rs. 50	Rs.23.04	199%	432%
IV.Worm infestation.	Rs. 12.75	Rs. 1.15	Rs. 0.74	1108%	1722%
V. Cost of 6 Month Treatment Course of Tuberculosis					
Using INH, Rifampicin, Pyrazinamide, Ethambutol According To WHO Guidelines	Rs. 2616	Rs. 1386.2	Rs. 1001.6	188%	261%
VI. Drug Costs for One Year's Treatment of Hypertension					
Using Atenolol 50 mg/Day	Rs. 766.5	Rs. 317.55	Rs. 58.4	241%	1312%
Using Nifedipine 30 mg/Day	Rs. 1095	Rs. 711.75	Rs. 87.6	153%	1250%
Using Enalapril 5 mg per day	Rs. 1076.75	Rs. 434.35	Rs. 87.6	248%	1229%

[2] Computed using the prices of the most and least expensive brands and using 100% markup over TNMSC tender rates. All drug price data from CIMS July 2003 issue and from Tamil Nadu Medical Services Corporation list which is effective till 2005)
for derivation of costs of treatment refer to Annexures 3 to 15.

VII. Drug Costs of Treatment of Epilepsy for One year					
Using Phenytoin 300 mg	Rs. 1303.05	Rs. 229.95	Rs.197.1	566%	661%
Carbamazepine 600 mg	Rs. 2014.8	Rs. 952.65	Rs. 262.8	211%	766%
Valproic Acid 1000 mg per Day	Rs. 3978.5	Rs. 3449.25	Rs. 2007.50	115%	198 %
VIII. Costs of Drug Treatment of Coronary Artery Disease for 1 Year					
Using Isosorbide Dinitrate 60 mg a day, Atenolol 50 mg a day, Aspirin 150 mg a day, Amlodipine 5 mg a day And Atorvastatin 10 mg a day	12541.4	2467.4	2007.5	508 %	624%
IX. Costs of Drug Treatment for 1 Year of Diabetes Mellitus Using Oral Drugs					
Using Glibenclamide 10 mg in Divided Doses	Rs. 649.7	Rs. 262.8	Rs. 73	247 %	890%
Using Glipizide 10 mg in Divided Doses	Rs. 803	Rs 459.9	Rs. 233.6	175%	344%
Using Gliclazide 80 mg in Divided Doses	Rs. 2073.2	Rs 912.5	Not in list	227%	----
Using Glimepride 2 mg per Day	Rs. 3660.95	Rs 795.7	Not in list	460%	-----
Using Metformin 1500 mg per dayin Divided Doses	Rs 1193.55	Rs. 657	Rs. 219	182%	545%
Using Pioglitazone 30 mg per Day	Rs. 2920	Rs. 638.75	Not in list	457%	----
X. Costs of 6 Months Treatment Course of Iron Deficiency Anemia					
Iron Salt + Folic Acid	Rs. 3744	Rs.216	Rs. 78	1733%	4800%

Drug Treatment Costs of Some Other Health Problems

XI: Drug Costs for Treatment of Drug (Choloroquine) Resistant Falciparum Malaria:

Using Oral Quinine sulphate	Rs. 210
Using inj. Artesunate	Rs. 972

XII*: Drug Costs for Treatment of Multidrug Resistant Tuberculosis for 18 Months According to Who Guidelines*

Using Amikacin, Ethionamide, ofloxacin, Ethambutol, Pyrazinamide,	Rs. 44,190

XIII: *Costs of Immunisation for Some Important Diseases: Hepatitis A*

Disease	Using most expensive brand	Using least expensive brand	Overpricing in immunisation costs
Hepatitis A	Rs. 1856	Rs.1424	130%
Typhoid using Vi capsular polysachharide antigen	Rs. 290	Rs. 187	155%

Annexure 1

A Note on Computation of Drug Costs and Assumptions Used

The costs of drug treatment calculated in Part II of the main section are assuming that the prescriber prescribes only what is rational and essential to the treatment of the illness. Most often the doctors prescribes additional vitamins, syrups, tonics, and other preparations of doubtful value which however inflate the costs of drug treatment significantly.

These drug costs should not be confused with costs of the treatment of a particular condition. If the cost has been calculated e.g. at Rs. 12541 per year for coronary artery disease, the actual costs of the entire disease are far higher because of costs of consultations, investigations, wages lost, travel etc. It would be in the area of at least Rs. 15,000 per year.

The cost of each drug treatment is computed using 3 different prices:
i. the highest priced mentioned in CIMS
ii. the lowest priced brand mentioned in CIMS,
iii. the third is 100% markup on the prices quoted by manufacturers for the tender of the Tamil Nadu Medical Services Corporation (hereafter referred to as TNMSC), which procures through a open tender (with adequate safeguards as to quality), drugs for the public health facilities of the state of Tamil Nadu. The entire process is transparent and the prices under the TNMSC procurement list have been taken from their website.

The prices quoted for the TNMSC tender would seem absurdly low when compared to the retail rate at which they are available in the market. The low prices are accounted by the fact that the manufacturers supply drugs directly to the TNMSC eliminating the role of middlemen. Also there are no promotional costs of these drugs. Keeping in mind the large volumes involved the manufacturers keep their profit margins more modest.

Drug	**Use of drug**	**Most expensive brand**	**TNMSC price**
Albendazole 400 mg	Worm infestation	Rs. 12.75	Rs. 0.37
Atenolol 50 mg	Hypertension	Rs. 2.1	Rs. 0.08
Amoxycillin 250 mg	Antibiotic for bacterial infections	Rs. 3.97	Rs. 0.61
Clotrimazole cream 1% 15 g	Antifungal	Rs. 24.90	Rs. 2.88
Enalapril 5 mg	Hypertension	Rs. 2.95	Rs. 0.06
Glibenclamide 5mg	Diabetes	Rs. 1.2	Rs. 0.05

in computation of the costs of various illness using the TNMSC price list a 100% markup has been added which would include quite a reasonable profit margin for the manufacture and the pharmaceutical trade. A 100% markup is being added to the TNMSC list on the generous assumption that the price at which a drug is being offered to the state of Tamil

Nadu is very close to the manufacturing cost of the drug, (which cannot of course be true because no manufacturer will sell a drug without a profit).

Annexure 2

Drug Cost of Treatment of Streptococcal Pharyngitis (bacterial sore throat)

The treatment of this condition consists of :
Cap Amoxicillin 250 mg 3 times a day for 10 days.

	NOVAMOX(Cipla)	DELAMIN (HAL)	TNMSC RATE
Costs of Cap. Amoxicillin	Rs. 3.97 per cap.	Rs. 2.6 per cap.	Rs. 0.61 per cap.

Drug cost of strep.pharyngitis	Drug cost using most expensive brand	Drug cost using least expensive brand	Drug cost using 100% markup over TNMSC price.
	Rs. 109.8 (Novamox, Ranbaxy)	Rs. 78 (139%)	Rs. 36.6(305%)

Annexure 3

Drug Cost of Treatment of Bacillary Dysentery

The treatment of this condition requires antibiotics along with Oral Rehydration Solution (ORS) administration.
i.e. for an adult : Norfloxacin 400 mg 2 times a day for 3 days + 5 packets of ORS each for 1 liter of solution.

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Costs of Norfloxacin			
	Most expensive brand. Norflox (Cipla)	Least expensive brand Biofloxin (BIOCHEM) .	TNMSC RATE.
Norfloxacin	: Rs. 4.7 per tab	Rs. 2.05	Rs. 0.54
Price of Oral Rehydration Solution			
	Punarjal (FDC).	Emlyte	TNMSC.
ORS packet for 1 lit. water	Rs.11.20	Rs. 9.60	Rs. 1.49

Drug cost of bacillary dysentery	Drug cost using most expensive brand of norfloxacin + expensive brand of ORS	Drug cost using least expensive brand norfloxacin + expensive brand of ORS	Drug cost using 100% markup over TNMSC price norfloxacin + price of ORS.
	Rs. 84.20	Rs. 60.30	Rs.21.48

Annexure 4

Drug Cost Treatment of Fungal Infections of Skin

The treatment of this condition requires administration of antifungal creams like 1% Clotrimazole for a few weeks, which may require upto 4 tubes of 15 g to be used.

	Most expensive brand Candid (Glenmark)	Least expensive brand Calcrem (Raptakos)	TNMSC
Clotrimazole cream 1% 15 g.	Rs. 24.90	Rs. 12.50	Rs. 2.88

Drug Costs of Treatment of Fungal Infection of Skin

Drug cost using most expensive brand of clotrimazole	Drug cost using least expensive brand of clotrimazole	Drug cost using 100% markup over TNMSC price of clotrimazole.
Rs. 99.6	Rs. 50	Rs.23.04

Annexure 5

Treatment of Worm Infestation

The treatment for most worm infestations consists of a single dose administration of a drug called albendazole.

	Most expensive brand Candid (Alkem)	Least expensive brand Tiobend (Cipla)	TNMSC
Albendazole 400 mg.	Rs. 12.75	Rs. 1.15	Rs. 0.37

Costs of Treatment of Worm Infestation

Drug cost using most expensive brand of albendazole	Drug cost using least expensive brand albendazole	Drug cost using 100% markup over TNMSC price of albendazole.
Rs. 12.75	Rs. 1.15	Rs.0.74

Annexure 6

Drug Cost of Treatment of Tuberculosis

The standard treatment of tuberculosis incorporates the use of 4 drugs in differing combinations for a period of 6 months .
These 4 firstline drugs are INH, Rifampicin, Ethambutol, Pyrazinamide.
in the first 2 months of treatment the regime for treatment of tuberculosis:
Is as follows:
INH 300 mg once daily + Rifampicin 450 mg once daily + Pyrazinamide 750 mg 2 tablets daily + Ethambutol 800 mg once daily.
Following this the drug regime for the next 4 months of treatment is as follows:
INH 300 mg once daily + Frifampicin 450 mg once daily .

Cost comparisons of first line anti tubercular drugs are –

Drug	Most expensive brand	Least expensive brand	TNMSC rate
Isoniazid (INH) 300 mg.	Rs. 0.79 per tab Isonex ()	Rs. 0.49 per tab Solonex ()	Rs. 0.17 per tab
Rifampicin 450 mg.	Rs. 8.09 per cap Macox (Macleods)	Rs. 4.43 per cap Famcin (IDPL)	Rs. 1.83 per cap
Pyrazinamide 750 mg Tab.	Rs. 6.5 per tab. P-zide (Cadila Pharma)	Rs. 3.04 per tab Tibimide (Themis)	Rs. 0.51 per tab. of 500 mg
Ethambutol 800 mg.	Rs. 3.96 Mycobutol(Cadila Pharma)	Rs. 1.36 Albutol (Alkem)	Rs. 0.85

Costs of 6 Months of Treatment with the Above Drugs Using Standard Treatment Guidelines of WHO

Costs of Treatment Using Expensive Brands	Costs of Treatment Using Least Expensive Brands	Costs of Treatment Using TNMSC Rates	Costs of Treatment Using 100% Markup Over TNMSC Rates
Rs. 2616	Rs. 1386.2	Rs. 502.8	Rs. 1001.6

Average Costs Per Day of Antitubercular Treatment Using Different Sources of Drugs.

Costs of Treatment Per Day Using Expensive Brands	Costs of Treatment Per Day Using Least Expensive Brands	Costs of Treatment Per Day Using TNMSC Rates	Costs of Treatment Per Day Using 100% Markup Over TNMSC Rates
Rs. 14.75	Rs. 7.70	Rs. 2.79	Rs. 5.56

Annexure 7

Drug Costs of Treatment of Hypertension

Hypertension has in recent years emerged as a major public health problem in india and is the cause of significant avoidable complications relating to the heart, brain, and kidney. Treatment of hypertension involves the use of different kinds of drugs each suited to particular patient types depending on the problem asoosciated with hypertentsion in a particular patient.

The different kinds of drugs used in hypertension and their average doses are as followed:
Atenolol : 50-100 mg/day.
Nifedipine: 20-30 mg/day.
Enalapril : 5-10 mg/day.

Drug	Most expensive brand	Least expensive brand	TNMSC rate
Atenolol 50 mg day	Rs. 2.1 Tenormin (ICI)	Rs. 0.87 BP-Nol (Elder)	Rs. 0.08
Nifedipine 10 mg	Rs. 1.0 Calcigard (Torrent)	Rs. 0.65 Cardipin (intas)	Rs. 0.04
Enalapril 5 mg	Rs. 2.95 Encardil (Medley)	Rs. 1.19 Enpril (Wockhardt)	Rs. 0.06

Costs Per Year of Antihypertensive Treatment Using Different Sources of Drugs

Drug dosage per day	Using cost of most expensive brand	Using cost of least expensive brand	Using cost of TNMSC tender rates	Using 100% markup over TNMSC rates
Atenolol 50 mg/day	Rs. 766.5	Rs. 317.55	Rs. 29.2	Rs. 58.4
Nifedipine 30 mg/day	Rs. 1095	Rs. 711.75	Rs. 43.8	Rs. 87.6
Enalapril 5 mg per day	Rs. 1076.75	Rs. 434.35	Rs. 43.8	Rs. 87.6

Annexure 8

Drug Costs in Treatment of Epilepsy

The treatment of epilepsy is also a long-term one requiring drug administration on a continuous basis for at least 3 years. The failure to take treatment can result in recurrent convulsions which can cause serious physical and psychological harm.

The average daily dose of some commonly used medications in epilepsy include the following:

Phenytoin : 300 mg once a day.
Carbamazepine : 600 mg in divided doses.
Valproic acid: 1000 mg in divided doses.

Drug	Most expensive brand	Least expensive brand	Cost after 100% markup over TNMSC rates
Phenytoin 300 mg	Rs. 3.57 Dilantin (Parke Davis) : Rs. 1.19 per 100 mg tab.	Rs. 0.63 Epileptin (IDPL) Rs. 0.21 per 100 mg tab.	Rs. 0.54 At Rs. 0.18 per 100 mg tab
Carbamazepine 600 mg	Rs. 5.52 Tegretol (Novartis): Rs. 1.84 per tab. of 200 mg	2.61 Cizetol(Cipla) : Rs.0.87 per tab. of 200 mg	Rs. 0.72 At Rs. 0.24 per tab. of 200 mg
Valproic acid 1000 mg per day	Rs. 10.9 Valtril (Wockhardt-Merind) Rs. 2.18 per tab. of 200 mg	Rs. 9.45 Encorate (Sun Pharma) Rs.1.89 per tab of 200 mg	Rs. 5.5 At Rs.1.1 per tab. of 200 mg

Drug Cost of One Year of Anti-epilepsy Treatment

Phenytoin 300 mg	Rs. 1303.05 Using Dilantin (Parke Davis) : Rs. 1.19 per 100 mg tab.	Rs. 229.95 Epileptin (IDPL) Rs. 0.21 per 100 mg tab.	Rs. 197.1
Carbamazepine 600 mg	Rs. 2014.8 Using Tegretol (Novartis): Rs. 1.84 per tab. of 200 mg	Rs. 952.65 Using Cizetol(Cipla) : Rs.0.87 per tab. of 200 mg	Rs. 262.8
Valproic acid 1000 mg per day	Rs. 3978.5 Using Valtril (Wockhardt-Merind) Rs. 2.18 per tab. of 200 mg	Rs. 3449.25 Using Encorate (Sun Pharma) Rs.1.89 per tab of 200 mg	Rs. 2007.5

Annexure 9

Drug Costs in Treatment of Coronary Artery Disease

The patient with coronary artery disease needs multiple medications. Very often they have associated diseases like hypertension, and diabetes mellitus which demand management. Moreover tight control of blood cholesterol is now increasingly advocated as part of the treatment strategy for coronary artery disease.
Therefore a typical prescription for a patient with coronary artery disease may read s follows:
Isosorbide dinitrate 20 mg three times a day.
Atenolol tablet 50 mg once a day.
Aspirin 150 mg once a day.
Tab. Atorvastatin 10 mg once a day.

Drug/dose	Most expensive brand	Least expensive brand	Cost of Rx with 100% markup over TNMSC rates
Isosorbide dinitrate 20 mg 3 times a day	Rs. 0.3 for a 10 mg tab Rx cost : Rs. 1.8 per day	Rs. 0.1 for a 10 mg tab. Rx cost : Rs. 0.6 per day	Rs. 0.08 Rx cost : Rs. 0.48 per day
Atenolol 50 mg once a day	Rs. 2.1 Tenormin (ICI)	Rs. 0.87 BP-Nol (Elder)	Rs. 0.16
Aspirin 150 mg	Rs. 0.85 Alpyrin (Lincoln)	Rs. 0.79 Delisprin (Otsira)	Rs. 0.10
Amlodipine 5 mg	Rs.4.81 Amlogard (Pfizer)	Rs. 0.5 Amlodac (Alidac)	Rs. 0.26
Atorvastatin 10 mg	Rs. 18 Atorlip(Cipla)	Rs. 4 Vasolip (JB Chemicals)	Not in list
Cost of Therapy Per Day	Rs. 27.56	Rs. 6.76	Rs. 1.0 per day plus cost of Atorvastatin. i.e. Rs. 4.5

Cost of One Year of Therapy of Coronary Artery Disease for 1 Year

Drug treatment costs	Costs using the most expensive brand	Costs using the least expensive brand	Costs using 100% markup over TNMSC rates and the cheapest brand

			of atorvastatin.
	12541.4	2467.4	Rs.2007.5

Annexure 10

Costs of Drug Treatment of Diabetes Mellitus

It is difficult to compute the costs of drug treatment of this condition because of the number of drugs which are used in its management. Oral drugs active in diabetes belong to four therapeutic categories.Some patients require insulin for control of blood glucose, which can of porcine, bovine or recombinant DNA origin.. Insulin prices themselves vary according to the type of insulin.

When it comes to oral drugs for diabetes, most agents in a particular class of drugs have a similar mechanism and magnitude of effect, and yet are widely different in costs. E.g. there is no fundamental difference in the action of drugs like glibenclamide, glipizide, glimepride, gliclazide. Glibenclamide and Glipizide being the oldest are also the cheapest, while some of the recent compounds are costly.

Prices of various oral antidiabetic drugs of the sulfonylurea class

	Most expensive brand	Least expensive brand	TNMSC price + 100% markup
Glibenclamide 5 mg	Rs. 0.89 G-nil(Mano)	Rs 0.36 Betanase (Alidac)	Rs. 0.1
Glipizide 5 mg	Rs. 1.1 D-Glip (Grandix)	Rs. 0.63 M-diab (Dominion)	Rs..32
Gliclazide 80 mg	Rs. 5.68 Diamicron (Serdia)	Rs. 2.5 Diatrol (Argus)	Not in list
Glimepride 2 mg	Rs. 10.03 Amaryl (Aventis)	Rs. 2.18 Gepride (Medley)	Not in list

Costs of Metformin

	Most expensive brand	Least expensive brand	TNMSC price + 100% markup
Metformin 500 mg	Rs.1.09 G-reg (mano)	Rs. 0.6 Etformin (Dey's)	Rs. 0.3

Recently introduced drugs for diabetes like Pioglitazone are again marked by high cost and marked price variation:

	Most expensive brand	
Pioglitazone 30 mg	Rs. 8.0 per tablet Piozone (Nicholas)	Rs. 1.75 per tablet. Pio-30 (Systopic)

The costs of treatment of Diabetes mellitus per day using average doses for the above drugs are as follows:

Cost of Daily Drug Treatment of Diabetes Using Various Drugs			
	Using most expensive brand	Using least expensive brand	Using drugs with 100 markup over TNMSC prices
Glibenclamide 10 mg in divided doses	Rs. 1.78	Rs. 0.72	Rs. 0.2
Glipizide 10 mg in divided doses	Rs. 2.2	Rs.1.26	Rs. 0.64
Gliclazide 80 mg in divided doses	Rs. 5.68	Rs.2.5	Not in TNMSC LIST
Glimepride 2 mg per day	Rs. 10.03	Rs.2.18	Not in TNMSC list
Metformin 1500 mg per day in divided doses	Rs. 3.27	Rs.1.8	Rs. 0.6
Pioglitazone 30 mg	Rs. 8.0	Rs.1.75	Not in TNMSC list

Costs of Drug Per Year for Treatment of Diabetes Mellitus

Glibenclamide 10 mg in divided doses	Rs. 649.7	Rs. 262.8	Rs. 73
Glipizide 10 mg in divided doses	Rs. 803	Rs 459.9	Rs. 233.6
Gliclazide 80 mg in divided doses	Rs. 2073.2	Rs 912.5	
Glimepride 2 mg per day	Rs. 3660.95	Rs 795.7	
Metformin 1500 mg per day in divided doses	Rs 1193.55	Rs. 657	Rs. 219
Pioglitazone	Rs. 2920	Rs. 638.75	

Annexure 11

Drug Costs for Treatment of Iron Deficiency Anemia

Anemia is a major public health problem in women and children with a prevalence of 74.3 in children of 6-35 months and a prevalence of 49-56% in women.(NFHS 1998/99)
Anemia in pregnant women has a number of detrimental effects. 20-40% of maternal mortality in india is accounted for by anemia. Anemia is also associated with the following complications of the fetus and mother:
Birth of low-birth weight babies.
Premature births.
Postpartum hemorrhage.
Anemia diminishes the work capacity of people,especially of those who are dependent on their physcial labor, and thereby has significant economic consequences.

The major cause of anemia is iron deficiency, often associated with folic acid deficiency caused by poor nutrition.

The treatment of iron-folic acid deficiency anemia is straightforward and in adults involves the administration of Ferrous sulphate in a dose of 200 mg three times (to give 180 mg elemental iron in a day) along with Folic acid 0.5 mg three times a day for a period of 4-6 months.

The above therapy is exceedingly cheap. A tablet of ferrous sulphate and folic acid with the above ingredients costs the TNMSC only Rs. .07 to buy, i.e. a mere 7 paise. Making the cost of therapy per day a mere 21 paise, and the entire course of treatment for 6 months: Rs. 38 rupees. Even if one were to buy a tablet of the above drug at 100% markup the cost of treatment would be Rs. 76 , and even at a 200% markup the cost of an entire course of treatment for 6 months would be only around 110 rupees.

All that is wrong with a part of the pharmaceutical sector in india is best seen in the area of preparations for iron deficiency anemia.

1. There are virtually no rational preparations for the treatment of iron deficiency anaemia.

Companies market iron salts in combination with a a bewildering number of constituents like vitamins, minerals, amino acids, trace elements, haemoglobin from slaughterhouse (was a popular and completely irrational constituent of preparations till its ban in 2000), stomach and liver extract just to increase the price of the preparation and to confuse the prescriber and the consumer without in any way adding to the therapeutic value.

There are virtually no preparations which do not sell the required constituents at a cost at least 10-20 times over the TNMSC the price mentioned above.
The National List of Essential Medicines mentions Ferrous Salt Tablets with iron equivalent to 60 mg elemental iron and Folic Acid Tablets 1 mg, 5 mg tablets as the preparations required for treatment of Iron and folic acid deficiency anemia

Only 2 out of the 131 brands listed in the July 2003 issue of CIMS contained the recommended combination of ferrous salt and folic acid. These are Fefol Spansule by Glaxo

Smith Kline, and Feroluv by Neu for eva with prices per tab. of Rs. 1.5 per tablet and Rs. 4.5 per tablet respectively. There are some others like Autrin and Conviron TR with added constituents like Vit B12, which is deemed unnecessary. of these Autrin with a price of Rs. 0.6 per tablet is the cheapest.

The cost of treatment of iron deficiency anemia with the above preparations like Autrin and Feroluv would be Rs. 1.2 and Rs. 9 per day respectively. This would make the cost of treatment over 6 months Rs. 216 and Rs. 1620 respectively.

The irrationality of the preparations tremendously increases the cost of therapy. The most glaring example of this is that of the best selling iron preparation Dexorange (Franco-indian). It is an unnecessary syrup based preparation, which is inappropriate for adults. It contains an iron salt in a ferric form which has an inferior rate of absorption compared to the ferrous form. Till 2000 this preparation also contained hemoglobin obtained from slaughterhouse blood, which was totally unnecessary, irrational and possibly hazardous.

Cost: Rs 46.30 inclusive of local taxes for a 200-ml bottle.
Iron Content per 15 ml : Ferric Ammonium citrate equivalent to 32 mg elemental iron per 15 ml. Therefore 60 mg elemental iron is present only in 30 ml of syrup.
Daily dose required to give 60 mg elemental iron three times a day: 90 ml.
Daily cost of therapy to obtain above levels of iron intake: Rs. 20.8
Cost of 1 month of therapy: Rs. 624
Cost of 6 months of therapy: Rs. 3744.

Cost of Treating Iron Deficiency Anemia for 6 Months Using Various Preparations in the Market

	Most expensive preparation. Syp. Dexorange	Least expensive preparation. Cap Autrin	Cost using TNMSC drug with 100% markup	Overpricing between brands	Overpricing between brand and TNMSC price with 100% markup
Iron-folic acid preparations	Rs. 3744	Rs. 216	Rs. 78	1733%	276%

The government has done precious little to protect the health and the interests of patients and consumers. There is continued irrationality in the content of iron preparations and lack of any rationale in their pricing which is detrimental to the health of lakhs of patients suffering from anemia.

It was only due to the persistent efforts of drug action groups that the Government belatedly banned the use of hemoglobin in iron preparations.

Annexure 12

Drug Costs of Treatment of Drug Resistant Malaria

1. Using Oral Quinine:

Dose: 10 mg/kg ~ 600 mg three times a day for 7 days.

Cost of oral Quinine: Rs. 5 for a 300 mg tab. (Quininga : inga)

Total cost of therapy : Rs. 210.

2. Using inj. Artesunate: (in severe drug resistant p.falciparum malaria).

Dose: 120 mg IM or IV on day 1 followed by 60 mg daily for 4 days.

Cost of inj. Artesunate: Rs. 162 for 60 mg.

Total cost of therapy : Rs. 972.

Annexure 13

Cost of Drug Treatment of Multi-Drug Resistant Tuberculosis

Source of drug dose: Guidelines for the management of drug resistant tuberculosis, World Health Organisation, 1998.

Source of drug prices: Current index of Medical Specialties, July 2003.

Computation of treatment costs (only Drugs) for an Indian patient with Multi-drug resistant Tuberculosis:

Cost of Drug Cost of Initial Phase of Treatment of 3 Months of Amikacin+ Ethionamide+ Ofloxacin + Pyrazinamide + Ethambutol.

Drug	Dose	Cost per day	Cost for 3 months
Amikacin +	0.75 g	Rs. 90	Rs. 8100
Ethionamide+	.75 g	Rs. 39	Rs. 3510
Pyrazinamide+	1.5 g	Rs. 10	Rs. 900
ofloxacin +	800 mg	Rs. 15	Rs. 1350
Ethambutol	800 mg	Rs. 3	Rs. 270
Total :		Rs. 157	Rs. 14130

The cost of therapy per day with these kind of drugs are $2^{1/2}$ times the minimum wage of a common man in india (Rs. 60). It would be important to remember that none of these drugs are presently under patent and therefore can be produced at a much lower cost.

Cost of Treatment of Maintenance Phase with Ethionamide+ Ethambutol+ Ofloxacin for 18 Months.

Drug	Dose	Cost per day	Cost for 18 months
Ethionamide+	.75 g	Rs. 39	Rs. 21060
ofloxacin +	800 mg	Rs. 15	Rs. 8100
Ethambutol	800 mg	Rs. 3	Rs. 1620
Total :		Rs. 50	Rs. 30780

Therefore the total cost of drugs for a patient of Multi-drug resistant Tuberculosis for a period of 18 months would be: Rs. 44,910.

A minimum wage worker would have to work for 737 days (more than 2 years)and put his entire wages into drug costs to pay for the course of Multidrug resistant tuberculosis. If we assume that the worker's family needs Rs. 25 for food, he would have to work for 5 years to pay for the treatment.

Annexure 14

Cost of Immunisation Against Some Diseases

Hepatitis A:

Immunisation schedule: 0.5 ml 2 injections.

Most expensive brand : Avaxim: (Aventis Pasteur) : Rs. 928 for 0.5 ml

Least expensive brand : Havrix: (GSK): Rs. 712.

TYPHOID IMMUNISATION USING PURIFIED VI CAPSULAR POLYSACCHARIDE ANTIGEN:

Dose schedule: 1 single injection for protection for 3 years.

Most expensive brand: Typhim Vi (Cadila Newgen) : Rs.290

Least expensive brand : Tyvax-Vi plus (VHB): Rs. 187.

CHAPTER 6

PHARMACEUTICAL POLICY (PP) 2002 AND NATIONAL HEALTH POLICY (NHP) 2002: DISCORDANCE IN PERSPECTIVES AND CONTENT

-Anurag Bhargava

From the National Health Policy 2003…	***From the National Pharmaceutical Policy 2002…***
Global experience has shown that the introduction of a TRIPS-consistent patent regime for drugs in a developing country results in an across-the-board increase in the cost of drugs and medical services. NHP-2002 will address itself to the future imperatives of health security in the country, in the post-TRIPS era.	…. two major issues have surfaced on account of globalization and implementation of our obligations under TRIPs which impact on long-term competitiveness of Indian industry. These have been addressed in the Pharmaceutical Policy-2002 *(not clear how except for this refererence –Editor)*
One nagging imperative, which has influenced every aspect of this Policy, is the need to ensure that 'equity' in the health sector stands as an independent goal. In any future evaluation of its success or failure, NHP-2002 would wish to be measured against this equity norm, rather than any other aggregated financial norm for the health sector. Consistent with the primacy given to 'equity', a marked emphasis has been provided in the policy for expanding and improving the primary health facilities, including the new concept of the provisioning of essential drugs through Central funding	A reorientation of the objectives of the current policy has also become necessary on account of these issues: The essentiality of improving incentives for research and development in the Indian pharmaceutical industry, to enable the industry to achieve sustainable growth particularly in view of anticipated changes in the Patent Law; and The need for reducing further the rigours of price control particularly in view of the ongoing process of liberalization.

The people of India are experiencing a crisis in public health. In many key indicators like infant mortality rate, maternal mortality rate, prevalence of anemia and malnutrition we fare very badly, and are far behind even some of our neighbors like Sri Lanka. While old diseases like tuberculosis, malaria, diarrheal diseases do not show signs of control and in fact are posing new problems due to drug resistance, we are being confronted with the new problems of the HIV epidemic and of a increasing prevalence of non-communicable diseases like diabetes, hypertension, ischemic heart disease,

cancers and respiratory disorders. With static and declining governmental expenditure on health, increasing use of user fees, increasing health care costs in the private sector the inequities in health are in fact on the increase.

The year 2002 saw the Government of India release two policy documents: the National Health Policy (NHP[1]) and the Pharmaceutical Policy (PP[2]) It would be reasonable to expect that the framing and the implementation of these two policies would be a coordinated effort, and to expect that these two policies would share the same perspective as medicines/pharmaceuticals are a vital and inseparable part of dealing with prevention and treatment of health problems at all levels of care. Thus if the National Health policy expresses concerns about the worldwide experience of the increase in the costs of drugs wherever the WTO regime takes effect without dilating on measures to be taken ,then it would be expected that these concerns would be addressed in greater detail in the pharmaceutical policy. If the National Health Policy mentionsthe diseases which pose important threats to public health, inadequacies of the present system of drug procurement, utilization and regulation, and some new initiatives likely to be undertaken to improve the access to low-priced quality drugs, then one would expect these to find resonance in the pharmaceutical policy.

But such expectations, reasonable though they may be are belied, when one compares the two policy documents. We would find striking discordance in perspectives and content which make one feel whether any public health perspective was taken into account at all in the framing of the pharmaceutical policy. To put it facetiously wth regard to drug related policies the left arm of the government does not seem to be aware what the right arm is upto. While the National Health Policy at least expresses concerns about the health problems being faced by people, the state of the public health system infrastructure, and the imperative of ensuring "equity,"the pharmaceutical policy document seems to be written purely as a document for the pharmaceutical industry with an overwhelming concern for its "stock equity", with scarcely a few lines about the end users of drugs the patients and their health problems.

The most plausible and charitable explanation for this peculiar disconnect between the two policies is the anomalous situation with regard to drugs which has prevailed in the country since independence. The manufacture as well as pricing of drugs comes under the purview of the Ministry of Chemicals and Fertilisers, and not under the Ministry of Health and Family Welfare as one would assume. The Health Policy is framed by the health ministry whie the pharmaceutical policy is framed by the Ministry of Chemicals and Fertilisers. Drug approval and licencses for manufacture of new drugs are given by the office of the Drug-Controller General which falls under the jurisdiction of the Ministry of Health. On the other hand all pricing issues are decided by the National Pharmaceutical Pharmaceutical Pricing Authority, which falls under the Ministry of Chemicals and Fertilisers.The government has avoided implementation of its own proposal of making a single overarching National Drug Authority to look into all drug

[1] Available at http://mohfw.nic.in

[2] (see http://www.nppaindia.nic.in/may-2002/policy-02.html)

related issues. The less charitable explanation for the disconnect between the two documents is that the pharmaceutical policy demonstrates the influence of the pharmacetical industry and trade on the formulators of the policy, something that the millions who suffer and die due to disease are not able to.

Illustrations of the Discordance in Perspective and Content

The following sections acts as an illustration of the wide discordance in perspectives and content between the two policies. We quote from the National Health Policy, add our comments and expectations from the PP 2002, and then report on what the PP 2002 had to say on the matter, with its implications.

Malaria

"Out of the communicable diseases which have persisted over time, the incidence of Malaria staged a resurgence in the1980s before stabilising at a fairly high prevalence level during the 1990s. Over the years, an increasing level of insecticide-resistance has developed in the malarial vectors in many parts of the country, while the incidence of the more deadly P-Falciparum Malaria has risen to about 50 percent in the country as a whole. " (NHP 2002)

Plasmodium .falciparum has become resistant to chloroquine necessitating the use of other antimalarials like quinine, and the newly discovered but now indigenously manufactured artemisinin derivatives. These alternative drugs are prohibitively expensive.

Given below are the comparative prices of chloroquine and these alternative drugs.

Table 1: Comparative Prices of Chloroquine vs. Alternative Drugs Required in Treatment of Chloroquine Resistant P.Falciparum Malaria

Drug	***Cost per tab.***	***Cost per injn.***
Chloroquine	Rs. 0.90 for a 250 mg tab	Rs. 3.46 for 200 mg
Quinine	Rs. 5.00 for a 300 mg tab	Rs. 18.00 for 600 mg
Artesunate	Rs. 22.00 for a 60 mg tab	Rs. 162/- for 60 mg

Ref: CIMS JULY 2003

As a result the drug costs for a the complete treatment of P.falciparum can now vary from Rs. 10 for a course of chloroquine to Rs. 210 for a course of oral quinine to Rs. 972 for a course of inj. Artesuate for severe malaria. It would be expected that some

measures to make these alternative drugs more affordable would have been planned. But the PP 2002 has nothing to say directly on this.

Table 2: Comparative Costs Of Treatment Of P.Falciparum Malaria Using Different Drugs

Oral chloroquine	Rs. 10
Oral quinine	Rs. 210
INJ. ARTESUNATE	Rs. 972

Ref: CIMS JULY 2003

Tuberculosis (TB)

"In respect of TB, the public health scenario has not shown any significant decline in the pool of infection amongst the community, and there has been a distressing trend in the increase of drug resistance in the type of infection prevailing in the country." (NHP)

Tuberculosis remains the leading infectious cause of death in India, killing close to 500,000 people per year. India has far more cases of tuberculosis than any other country in the world- about 2 million new cases per year, and accounts for nearly one third of the prevalent cases globally. (Khatri GK, Freiden TR Controlling Tuberculosis in India *N Engl J Med* 2002. 347:1420-5.)

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Among the major problems with treatment of TB are: the increasing prevalence of drug resistance in patients with Tuberculosis; and cost of treatment of a single patient with multi-drug resistant TB can be 50 times the cost of a treatment of a single patient with drug sensitive TB:

Table 3: Costs of Drugs Used in Management of Drug Resistant Tuberculosis

Drug	Price per tab.	Cost of Rx per day
Ethionamide	13.00 for 250 mg	Rs. 26-52 for 0.5 g-1.0 g/day.
Ofloxacin	Rs. 4.00 for 200 mg	Rs. 12–16 for 600–800 mg/day
Amikacin	Rs. 60.0 for 500 mg	Rs. 90-120 for 750 mg/day
Capreomycin	Rs. 204 for 0.75 g	Rs. 204-275 for 0.75-1g/day
Cycloserine	Rs. 30 for 250 mg	Rs. 60-90 for 0.5-0.75 g/day
Prothionamide	Rs. 15 for 250 mg	Rs. 30-45 for 0.5-0.75g/day.

Ref: CIMS JULY 2003

What are the cost implications of TB drugs for the TB patient? The cost of therapy per day with these kinds of drugs would be easily 4-5 times the minimum wage of a common man in India. None of these drugs are presently under patent and therefore can be produced at a much lower cost.

What could we have expected from PP 2002? That since TB is the largest single cause of death, and because drug resistance is increasing, the PP 2002 should have had the goal of lower cost antituberculosis drugs, both first line as well as second line drugs used for drug-resistant TB as a priority item. But the PP 2002 has nothing to offer us on these problems.

HIV/AIDS

"A new and extremely virulent communicable disease – HIV/AIDS - has emerged on the health scene since the declaration of the NHP-1983. As there is no existing therapeutic cure or vaccine for this infection, the disease constitutes a serious threat, not merely to public health but to economic development in the country." (NHP)

AIDS epidemic in India has already affected 4 million people. Antiretroviral therapy can dramatically change in quality of life, life expectancy, the risks of mother-to-child transmission. Cost of antiretrovirals therapy is prohibitive. However Indian companies have shown the way by offering in the international market antiretrovirals at 3% of the international rates. The Government of India is fighting shy of providing drugs free of cost to AIDS patients. PP 2002 should have seen the need to support them by

appropriate policy initiatives. The PP 2002 has no thinking to offer on policies for provision of low-cost antiretrovirals to the HIV affected people of India, at the very least for prevention of mother-to-child .

Table 4 : Costs of Some Antiretrovirals in India

Drug	Cost Per Tab.	Dose Per Day	Cost Of Rx Per Day
Zidovudine	Rs. 12 for a 100 mg tab.	200 mg 8 hourly	Rs. 72
Lamivudine	Rs 20 for a 150 mg tab.	150 mg 12 hourly	Rs. 40
Nevirapine	Rs. 39 for a 200 mg tab.	200 mg per day	Rs. 39
Lamivudine+ Zidovudine	Rs. 51 for a tab.	1 tab. 12 hourly	Rs. 100

Note: Prices of CIPLA products quoted in CIMS, July 2003.

Water-borne Infections

"The common water-borne infections – Gastroenteritis, Cholera, and some forms of Hepatitis – continue to contribute to a high level of morbidity in the population, even though the mortality rate may have been somewhat moderated." (NHP)

There are an estimated 19 crore illness episodes of diarrhea per year in the under-fives in India which contribute substantially to mortality of under-fives.
The most important drug for diarrheal diseases is oral rehydration solution.
Currently ORS is available at Rs. 12 for a pack for making a 1 liter solution.
ORS is out of drug price control, which accounts for its high price.
Improved vaccines against some of these water-borne diseases are now available, which are not part of the National Immunisation Programme.
These vaccines are prohibitively expensive. The PP 2002 has nothing to say about putting ORS and these vaccines under price control

Table 6: Costs of Some Newer Vaccines for Water-Borne Diseases

Disease	Medicine	Cost
Hepatitis A	Havrix (Glaxo)	Rs. 1424 for a course of 2 injections.
Typhoid	Typhoral	Rs. 275 for a course of 3 caps

Ref: CIMS July 2003

Diabetes, Cancer, Cardiovascular Diseases

" The period after the announcement of NHP-83 has also seen an increase in **mortality** through 'life-style' diseases- diabetes, cancer and cardiovascular diseases." (NHP)

Changes in demography, lifestyle and diet have seen the increasing prevalence of these diseases, which are now a major cause of morbidity and mortality. Some of these disorders demand lifelong medication (diabetes, hypertension) while others like cancer require highly expensive therapy for their treatment and cure.

What could the PP 2002 done in this regard? Because of the long term therapy required in these disorders, all drugs related to cancer, diabetes, hypertension need to be under price control. Now only some of the required drugs are in price control because of price control criteria of turnover, etc.

Macronutrient and Micronutrient Deficiencies

"Another area of grave concern in the public health domain is the persistent incidence of macro and micro nutrient deficiencies, especially among women and children. In the vulnerable sub-category of women and the girl child, this has the multiplier effect through the birth of low birth weight babies and serious ramifications of the consequential mental and physical retarded growth." (NHP)

How bad is the nutritional deficiency anemia situation in India? Iron deficiency anemia is a major national problem. It causes low birth weight, growth retardation of children and high proportion of women dying at delivery or during pregnancy. Indian market has no simple low cost iron folic acid preparation at the retail level. On the contrary a lot of irrational, unscientific, high cost preparations are available. Newly introduced preparations like iron hydroxide polymaltose are highly expensive and have been shown in studies to be almost completely ineffective. Iron preparations have never been placed under price control. More simple iron-folic acid tablets are not available easily in the retail market.

What is the least expectation from PP 2002? Policies to make available rational low-cost iron preparations and disallow production, and promotion of banned, irrational combinations in the market and to put iron and folic acid preparations under price control.

There is no mention in PP 2002 of any public health problem and their drug requirements including anemia.

The fact that the most commonly prevalent disorder which diminishes the work capacity of the Indian people, the growth potential of its children, contributes to a significant part of its maternal mortality doesn't merit any intervention in the policy speaks volumes about its orientation. The fact that people would have to spend anywhere from Rs. 3 to Rs. 21 a day on the treatment of anemia which should be possible at 20% to 3 % of that cost respectively as a result of these policies does not matter.

The exclusion of anemia preparations from the list of drugs under price control would rank among its most glaring and astounding omissions that have made pharmaceutical manufacturers flood the market with all kinds of irrational formulations at irrational prices.

What the NHP Recognises and the PP 2002 Underplays/Ignores

"This Policy emphasizes the need for basing treatment regimens, in both the public and private domain, on a limited number of essential drugs of a generic nature. This is a pre-requisite for cost-effective public health care." (NHP)

The NHP also emphasises inadequacy of public health expenditure; burden of rising health costs on the consumer and equity in Public Health. On the other hand the PP 2002 does not anywhere mention public health problems like falciparum malaria, tuberculosis, HIV disease, water-borne diseases, hypertension, diabetes, cancer, and macro and micronutrient deficiency and their specific drug requirements. And policy prescriptions thereof. Or for that matter Issues of registration of manufacturers, registration of formulations and restricting their number, scarcity of drug inspectors and drug quality testing labs, very high trade margins, presence of irrational, ineffective, and hazardous drugs in the market etc.

What the PP 2002 could have done?

- Recognise the aim of PP policy is for the health of the people. Therefore drugs have to be affordable.
- Put all essential drugs under price control.
- Clear registry of all drugs and formulations made in India accessible to everybody.
- Stringent checks on spuriousness, corruption and drug industry-trade-medical profession-regulatory authority nexus.
- Ban on irrational, hazardous formulations across the board instead of piece by piece examination.
- Use of TRIPS/WTO provisions to make drugs cheaper in India (and be a beacon for developing and underdeveloped countries).

Conclusion

The above discussion clearly shows that the National Health Policy has some public health perspective, while the pharmaceutical policy 2002 is devoid of any. The policy clearly has only an industry perspective, which seems to be structured and oriented towards lessening the rigours of price control (which is a peculiar term for a mechanism which allows the retail cost of drugs to have 100% post manufacturing expenses). It seems to matters little to this policy formulation the kind of diseases which people have to suffer from, their needs for low-cost quality drugs, and the concerns that the post-WTO scenario would increase the costs and limit access to drugs, especially to poor people. If the national health policy talks in detail about public health problems and the

pharmaceutical policy responds with a deafening silence, then the whole exercise could be termed an academic one, aimed at political correctness rather than corrective action. The concern for equity highlighted in the national health policy is clearly lacking in this document.

For all those who are concerned with the health of people it offers no solace in the form of better access to essential drugs that meet people's health needs at lower cost. What it offers is totally arbitrarily defined criteria for deciding the list of price-controlled drugs, which shall ensure that even the present shortened and anomalous list of drugs under price control would undergo further pruning.

The fact that an important policy like the pharmaceutical policy can be so out of tune with the interests and concerns of the people for whom it has been formulated is a revealing one. And yet it is this policy and its provisions which shall determine how much money people will pay all over the country for relief of their pains, for treatment of their diarrhea, malaria, or tuberculosis, which shall determine how much more unaffordable will drugs for hypertension, diabetes be, how much debt will they incur on their treatment costs and with what effect on their lives? That is if one could really call what a large number of people in India live as a life, rather than survival, forever on the edge.

CHAPTER 7

PRICE CONTROL POLICY AND PUBLIC HEALTH:

IRRELEVANCE AND DANGER OF APPLYING ONLY ECONOMIC CRITERIA

--Anurag Bhargava

There is increasing concern about the rising costs of health care in India. National Sample Surveys from the mid 1980s and 1990s point to significant increases in the cost of both in-patient and out-patient health care in rural and urban areas. Drug costs and rising fees for different health services undoubtedly played a major role in this. According to NSS data, in the 1990s. Compared to 1986-87, the proportion of those who said they were unable to access health care because of 'financial reasons' went up significantly in both rural and urban areas.

With the objective of making essential drugs available to the people, the Government has been implementing drug price control orders (DPCO) since 1979. The first order covered 347 drugs and included all the drugs, which were deemed essential to meeting India's public health problems. But over the years, with the changing socio-political climate and perhaps pressure from the influential pharmaceutical industry, the span of these price control orders has been reduced successively. Another regressive trend has been the increasing divergence between the priorities of public health in India and the drugs covered under the DPCO.

The 1995 drug price order is the last price control order to have been implemented. It was the first such order in the decade of accelerated economic reforms in the country. It was decided in 1994 (as described in the modification of the drug policy 1986) to employ criteria based on retail sales of drugs as recorded by a private organisation ORG to decide the list of drugs to be brought under price control. Only drugs with annual turnover greater than 4 crores, where there was insufficient competition (defined by one formulator having more than 40% share of the market inspite of having at least 5 bulk producers and 10 formulators) were to be considered for price control. Monopoly situations in which any formulator with an annual turnover greater than 1 crore in which a single formulator had more than 90% share were also to be covered under price control. All other drugs and formulations were to be exempt from price control. The policy modification of the drug policy 1986 and the order did not take into account any other factor like the essentiality of the drug, and its need for meeting the priority health care needs of people.

The application of these criteria in the 1995 order saw the number of drugs whose prices were regulated cut to 74 from the previous 142, covered by Drug Price control order 1987. But what did it do to the drugs which are needed to meet the public health problems? An analysis of the list of drugs listed for price control in the DPCO (Drug Price Control Order) 1995 is necessary to understand the danger and irrelevance of the

economic criteria in the 1995 drug policy. as also that which is offered in Pharmaceutical Policy 2002

What is striking in this analysis is that the drugs for a majority of public health problems are either under-represented or unrepresented, which is a matter of serious concern. Also we find that many drugs are surprisingly included in the list even if non-essential, or even hazardous in nature. The reader is invited to study Table 1.

Table 1: Public Health Problems and their Absence in the Drug Price Control Basket

Public health problem	**Drugs required for the problem**	**Drug listed in 1995 DPCO for the problem**	**Remarks**
1. Iron Deficiency anemia	Ferrous sulphate Folic acid	NONE	Anemia is a major public health problem in women and children with a prevalence of 74.3 in children of 6-35 months and a prevalence of 49-56% in women .(NFHS 1998/99) Anemia contributes to 1/3 of maternal mortaltiy. Exclusion is against interests of public health.
2. Tuberculosis	INH, Rifampicin, Ethambutol, Pyrazinamide. Also in view of the increasing prevalence of drug resistant TB, drugs like Ofloxacin, Ethionamide, Cycloserine, which are required but are exhorbitantly priced should be included	Rifampicin	TB is the single largest killer disease in India with 5 lakh deaths per year. According to WHO estimates TB patients spend Rs.645 crore on private TB care in 1997 (Ref. TB in India: WHO SEARO). Rural patients have to spend Rs.1000 per month on diagnosis and treatment which invariably results in mortgaging of assets and valuables
3.Malaria including chloroquine resistant falciparum malaria which has become prevalent in many parts of	Chloroquine, Primaquine, Quinine	Chloroquine	Quinine is essential in treatment of chloroquine resistant falciparum malaria which can otherwise be fatal amd which is

India.			increasing in its prevalence in India.
4. HIV disease/AIDS	Zidovudine, Lamivudine, Nevirapine, Indinavir,	NONE	India has the second highest number of HIV disease patients in the world.(3-4 million) Yet no drug under price controls to make them more affordable.
4.Agents to prevent dehydration in diarrheal diseases. Dehydration due to diarrheal diseases killls thousands of children every year in India.	Oral Rehydration Salts	NONE	1 lakh children under 5 years of age die due to diarrhea and dehydration. There are more than 1 crore diarrheal episodes/year Why is ORS then not represented?
4. Leprosy	Dapsone, Clofazimine, Rifampicin	Rifampicin	the exclusion of the other 2 drugs which are used in greater quantities is inexplicable
6. Filariasis	Diethylcarbamazine citrate	NONE	6 million Indians develop acute filaria and 45 million have chronic filarial lesions.
7. Hypertension	Atenolol, Enalapril, Hydrochlorthiazide, Amlodipine	Captopril, Methyldopa	Hypertension is an increasingly common problem in rural andurban areas Different kinds of antihypertensives are required depending on the patient's associated conditions.
8. Coronary artery disease:	Glyceryl trinitrate, Isosorbide dinitrate, Beta blocker, Calcium blocker	NONE	Coronary artery disease has prevalence of 80-120/1000 in urban areas, and 30-60/1000 persons. Drugs for such a problem should be there in such a list.

9.Vaccines (new) for Rabies, Hepatitis B: Rabies kills thousands of people every year in India. Hepatitis B is an important public health problem which causes acute, chronic hepatitis and liver cancer.	Cell culture derived rabies vaccine. The current vaccines for rabies are very expensive.The old vaccine based on sheep brain is outdated and occasionally hazardous.	NONE	Nearly 1.1-1.5 million people are administered rabies vaccine every year. The reported mortality with rabies is 30000-40000 per year, which is an underestimation. A single dose of cell culture derived costs Rs.300 in the market.As in the immunization of a single patient 5 doses are required, the cost per patient turns out to be Rs.1500, which is beyond the reach of the poor.
10. CANCER: Over 7 lakh patients develop cancer every year	Many drugs are available which are however prohibitively expensive which can play a curative or palliative role in different types of cancer .	NONE	Many forms of cancer especially in children and many in adults are completely curable with effective chemotherapy. However anti-cancer drugs are mainly still sourced from abroad, and are prohibitively expensive. They can costs thousands of rupees per dose.
11. Sera for use in tetanus, diphtheria, Rh isoimmunisation.	Anti-tetanus serum Anti-diphtheria antitoxin Anti-D immunoglobulin	NONE	Its exclusion is inexplicable

12. Analgesic-antipyretic: Fever and pain are the most common of symptoms which need to be relieved	Paracetamol is the drug of choice for relief of fever and is a safe analgesic	Paracetamol is excluded from the list	The exclusion of this drug, which is essential, and of mass consumption defies logic.
13. Anticonvulsants	Phenytoin, Carbamazepine, Valproic acid	NONE	Seizure disorders are common and require prolonged even lifelong therapy and should have been included

The authorities of the Govt of India seem to have erred seriously not only by excluding drugs which were required in the interest of public health in India but also including in the list many drugs, which are non-essential, outdated and even hazardous. See Table 2.

Table 2: Examples of Non-Essential, Outdated and Hazardous Drugs From DPCO 1995

Name Of Drug	**Remark**
1.Analgin(Metamizole)	Hazardous . Can cause serious blood disorders. Banned even for use in animals in the USA.
2. Phenylbutazone	Hazardous. Can cause serious blood disorders.
3. Sulphadimidine	Outdated
4. Vitamin E	No clear therapeutic value. Non-essential. It is not mentioned in any essential drug list in the world.
5. Mebhydrolin	Non-essential
6. Diosmine	Non-essential
7. Panthonate and panthenols.	Non-essential
8. Bacampicilin	Non-essential.Other cheaper alternatives exist.

The 1995 list of drugs under price control has been analysed in detail in order to arrive at an understanding of what can happen if sales and market share based criteria rather than public health priority based criteria are followed in drafting a price control order. The result of application of such criteria very clearly produces a list of drug antithetical to the interests of millions of Indians suffering the burden of public health problems in a situation where private expenditure health is 80% of the total.

If a list can exclude essential drugs for public health problems like ORS, drugs for anemia, drugs for tuberculosis, malaria, leprosy, filariasis, vaccines for killer diseases, drugs for major non-communicable diseases like hypertension, coronary artery disease, cancer, and exclude a drug like paracetamol, then what is the relevance of such a list for India?

If a list can include drugs like analgin, which is banned almost all over the world, include a drug like Vitamin E, which has no clear therapeutic value, rather than Vit. B_{12} and Vit. D which do have, and include a host of non-essential and even hazardous drugs at the cost of drugs which have been mentioned above, then is the logic or rationale behind the framing of such a list not deeply flawed ?

The process of selection of drugs for the 1995 list is clearly against all priorities of public health in India. It results in essential drugs to be used in public health problems escaping price control and becoming more expensive. The perpetuation of this use of selective and arbitrary market sales and share based criteria in the pharmaceutical policy 2002 is bound to worsen the divergence between public health interests and the policy which was supposed to serve them. The pharmaceutical policy of 2002 does intend to apply these criteria to the National Essential Drug List of 1996, but given the kind of turnover and share based criteria which are now being suggested in the Pharmaceutical policy it will again produce anomalous price control orders with lists of drugs like the one of 1995..
In a country like India where 40% of the people live below the poverty line, who have make virtually all the expenses for health care out of pocket, where communicable diseases kill hundreds of thousands of people annually, public health interests should dictate the framing of the drug policy rather than arbitrarily defined sales criteria based on turnover.

CHAPTER 8

DRUGS LIKELY TO GO OUT OF PRICE CONTROL AFTER PP 2002 AND THE ONES REMAINING

1. Drugs In Price Control As Per DPCO 1995 Going Out Of Price Control Basket After Pharma Policy 2002 Is Implemented

(One crore = 10 million and One US $ = Rs 50/- approx.)

Sr. No.	**Molecules**	**Main Use**	**Value *Rs. Crores* ORG March 2001**	**Brand Leader**	**Company**	**Value *Rs. Crores* ORG March 2001**	**Market Share % age**
1.	Pencillin	Antimicrobial/Antibiotic	55.06	Pentids	Sarabhai Piramal	19.78	35.92
				Penidure	Wyth Lederle	10.44	
2.	Tetracycline	Antimicrobial/Antibiotic	28.00	Restcycline	Sarabhai Piramal	11.04	39.43
				Hospacycline	Hoechst Marion Russel	9.05	
3.	Ranitidine	Hyper Acidity/ Gastric Antiulcer	148.04	Zinetac	Glaxo SKB	60.59	40.93
				Aciloc	Cadila Pharma	33.49	
4.	Vitamin C	Vitamin deficiency/ Nutrition Suppl	21.00	Celin	GSKB	11.34	54.00
				Limcee	Sarabhai Piramal	5.50	
5.	Doxcycline	Antibiotic	64.88	Doxy-1	USV	18.74	28.88
				Vivazine	Medbios Labs	10.40	
6.	Ciprofloxacin	Antimicrobial/Antibiotic	322.99	Cifran	Ranbaxy	56.64	17.54
				Ciplox	Cipla	41.20	
7.	Dexametha-sone	Steroid/ Anti asthmatic	47.78	Dexona	Zydus Cadila	20.05	41.96
				Decdan	Wockhardt	11.30	

					Merind		
8.	Carbamaze-pine	Antiepileptic	75.85	Tegrital	Novartis	43.18	45.06
				Zen	Intas	10.29	
9.	Gentamycin	Antimicrobial/Antibiotic	34.91	Genticyn	Nicholas Piramal	11.99	34.35
				Gentamycin	Wockhardt Merind	5.30	
10.	Vitamin A	Vitamin Suppl	8.56	Vitamin A	USV Ltd	6.84	79.91
				Vit-A	Nicholas Piramal	1.01	
11.	Famotidine	Hyper acidity/ Gastric Antiulcer	27.22	Topcid	Torrent	5.55	20.39
				Famtec	Nicholas Piramal	5.04	
12.	Insulin	Anti-diabetic	161.77	Human Mixtard	Knoll Pharma	43.80	27.08
				Mixtard	Knoll Pharma	20.80	
13.	Asprin	Analgesic Antiplatelet	33.56	Ecosprin	USV	16.35	48.72
				Asa-50	German Remedies	7.60	
14.	Cefadroxyl	Antimicrobial/Antibiotic	128.83	Cefadrox	Aristo-Pharma	18.11	14.06
				Droxyl	Torrent	15.35	
15.	Captopril	Anti hyper-tensives/ ACE Inhibitor	2.59	Acetan	WMR	2.59	100.00
				Captopril	Lupin Labs	0.00	
16.	Pentaxy-fyline	Peripheral Vasodilator	12.80	Trental	Hoechst	10.90	85.16
				Flexital	Sun Pharma	1.15	
17.	Naproxen	Anti-inflammatory Analgesic	10.59	Naprosyn	RPG Life Science	5.33	50.33
				Xenobid	Rallis Pharma	3.87	
18.	Vitamin B2 Ribolabin	Vitamin Suppl	0.66	Raboflabin	Rallis Pharma	0.66	100.00
19.	Levodopa	Antiparkin-sonism	0.13	Lebopa	Wallace Pharma	0.12	92.31
20.	Tolnaftate	Topical antibacterial &	2.91	Tinaderm	Fulford	2.85	97.94

		antifungal					
21.	Nalidixic Acid	Antidiarroheal/anti-infective	7.47	Gramoneg	Ranbaxy	6.48	86.76
				Diarlop	Jagson Pal	0.64	
22.	Dextropro-poxyyphene	Analgesic	0.17	Parvodex	Micro Labs	0.17	100.00
23.	Salfadoxine	Antimalarial	0.00	Pyralifin	Lupin	0.00	
24.	Cloxacillin	Antibacterial	1.97	Klox	Lykalabs	1.89	95.94
				Cloxin	Sur Pharma	0.03	
25.	Spironolactone	Diuretic	3.27	Aldactone	RPG	3.27	10.00
26.	Chloroxylenol	Antiseptic	20.06	Dettol	Reckitt & Coleman	18.60	92.72
27.	Chlorpropamide	Anti-diabetic	0.15	Copamide	Dey's Medical Store	0.15	100.00
28.	Chlorpromazine	Anti psychotic	1.73	Chlorpromazine	Sun Pharma	0.54	31.21
				Tranchlor	Medo Pharma	0.53	
29.	Phenyl Butazone	Anti-inflammatory	0.05	Phenyl Butazone	Paam Pharma	0.05	100.00
30.	Tri mipramine	Anti depressant	0.52	Surmontil	Rhone Poulenc	0.52	100.00
31.	Cefazolin	Antibiotic	4.22	Deflin	Ranbaxy	4.06	96.21
				Azolin	Biochem	0.09	
32.	Analgin	Analgestic/ Antipyretic	23.95	Novalgin	Hoechst Marion Russel	13.73	57.33
				Baralgin-M	Hoechst Marion Russel	4.53	
33.	Furazolidone	Anti amoebicide	1.94	Furoxone	Smith Kline Beecham	1.93	99.48
				Furazolidone	Paam Pharma	0.01	
34.	Verapamil	Anti Hypertensive	7.44	Calaplin	Nicholas Piramal	6.35	85.35
				Calaplin	Nicholas Piramal	1.08	
35.	Vitamin B1	Vitamin Suppl	0.45	Benalgis	Fanco Indian	0.44	97.78
					Cyper Pharma	0.01	
36.	Sulaphamoxol	Antibacterial	0.07	Sulfuno	German	0.07	100.00

	e				Remedies		
37.	Sulphadiazine	Antibacterial	0.01	Sulphadiazine	Rhone Poulenc	0.01	100.00
38.	Griseofulvin	Antifungal	21.18	Grisovin-FP	GSK	7.28	34.37
				Griso OD	American Remedies	5.17	
39.	Frusemid	Diuretic	9.48	Lasix	HMR	9.23	97.36
				Frusenex	Geno Pharma	0.25	
40.	Salazosulphapyrine	Analgesic/ IBS	6.57	Sazo-EN	Wallace	5.92	90.11
				Salazopyrin	Wallace	0.65	
41.	Diosmin	Homeostatic and Anti haemorrhagic	5.81	Venusmin	Martin & Harris	4.04	69.54
				Venex	Elder Pharma	1.67	
42.	Lincomycin	Antibacterial	9.92	Lynx	Wallace	9.90	99.80
43.	Sulphadimidine	Antibacterial	0.04	Sulphadimidine	Cyber Pharma	0.04	100.00
44.	Methyl dopa	Anti hypertensive	5.14	Alphadopa	Wockhardt Merind	5.07	98.64
				Sembrina	Nicholas Piramal	0.07	
45.	Sulphamethoxazole	Antibacterial (not used in plain)					
46.	Oxytetracycline	Antibacterial	19.62	Terramycine	Pfizer	12.20	62.18
47.	Trimethoprim	Antibacterial					
48.	Vitamin E	Vitamin Suppl	73.67	Evion	E-Merck	40.02	54.32
				Bio-E	American Remedies	9.26	

2. List of Price Controlled Bulk Drugs of (DPCO 1995) that will Remain After PP 2002

1. Amodiaquin
2. Becampicillin
3. Betamethasone
4. Cefotaxime
5. Chloroquine
6. Ephedrine
7. Erythromycin
8. Framycetin
9. *Glipizide*
10. Halogenated Hydroxyquinoline
11. Ibuprofen
12. Lynestranol
13. Mebhydroline
14. *Methendienone*
15. Metronidazole
16. Norfloxacin
17. *Panthonates & Panthenols*
18. Pentazocine
19. Pheniramine Maleate
20. Prednisolone
21. Pyrental
22. Pyrithioxine
23. Rifampicin
24. Salazosulphapyrine
25. Salbutamol
26. Theophylline
27.

(itals: corresponding formulations not in the list below).

3. List of Price Controlled Formulations of (DPCO 1995) that will Remain after PP 2002

Consolidated Ceiling Prices of Formulations based on:

1. Aminophilline
2. Amodiaquin
3. Becampicillin
4. Betamethasone
5. Cefotaxime
6. Chloroquine
7. Dcmx
8. Ephedrine
9. Erythromycin
10. Ibuprofen
11. Ichq
12. Mebhydroline
13. Methyldopa
14. Metronidazole
15. Framycetin
16. Norfloxacin
17. Pcmx
18. Pentazocine
19. Pheniramine Maleate
20. Prednisolone
21. Pyrental
22. Rifampicin
23. Salazosulphapyrine
24. Salbutamol
25. Streptomycin
26. Theophylline
27. Vitamin Combination Preparations

CHAPTER 9: PRICING OF DRUGS NOT IN PRICE CONTROL AS PER DPCO & NPPA COSTING NORMS*

Name	Use	Selling Price after 100 % mark up per 10 Tabs/Caps *	Present MRP in market of a similar product	Brand Name of similar product	Name of Manu-facturer	% of MRP to 100 % MAPE price
1	2	3	4	5	6	7
Acyclovir Tabs 800 mg	Antiviral useful in AIDS, herpes, etc.	104.22	187	Acivir DT	CIPLA	179
Albendazole Tabs 400 mg	For treatment of worms	10.13	123.70	Combantrin - A	Pfizer	1221
Amlodipine Tabs 5 mg	For High Blood Pressure	1.67	48.13	Amloguard	Pfizer	2882
Amoxycillin Caps 250 mg	Antibiotic	11.96	30.01	Twicyl	Bio-Evans	251
Atenolol Tabs 50 mg	Myocardial Infarction, High BP, Angina.	3.50	21.00	Atenova	Lupin	600
Cephalexin Caps 500 mg	Antibiotic	34.92	129.00	Ceff	Lupin	369
Cetrizine Tabs 10 mg	Anti-allergic	1.40	26.10	Cetrizet	Sun	1864
Diazepam Tabs 5 mg	Sedative	1.05	14.00	Calmpose	Ranbaxy	1333
Enalapril Maleate Tabs 5mg	Antihypertensive, For Congestive Heart failure and other Cardiac conditions	1.73	19.00	Nuril	US Vitamins	1098
Ethambutol Tabs 800mg	Anti TB, Anti Leprosy	21.47	34.00	Mycobutol	Cadila	158
Fluconazole Caps 150mg	Anti fungal, also used as an adjunctive in AIDS treatment	20.38	106.88	Alfucoz	Alembic	524
Glibenclamide Tabs 5mg	Anti diabetic	1.10	6.60	Daonil	Aventis	600
Hydrochlorothiazide Tabs 25 mg	Diuretic	1.38	15.00	Hydride	Micro Lab	1087
Indomethacin Caps 25 mg	Rheumatoid Arthritis, Gout	4.44	14.90	Artisid	Sun	336

Name	Use	Selling Price after 100 % mark up per 10 Tabs/Caps	Present MRP in market	Brand Name of similar product	Name of Manu-facturer	% of MRP to 100 % MAPE price
1	2	3	4	5	6	7
Isoniazid Tabs 300 mg	Anti TB.	306.00 per Bulk pack of 1000 Tabs	795.24 per Bulk pack of 1000 Tabs	Isonex	Pfizer	260
Mebendazole Tabs	For treatment of worms	2.26	13.25	Mebex	Cipla	586
Metformin HCl Tabs 500mg (S)	Anti diabetic	3.47	10.40	Glumet	Cipla	300
Metoclopramide Tabs 10 mg	Anti vomitting	1.54	10.60	Perinorm	IPCA	688
Ofloxacin Tabs 400 mg	Antibiotic	37.72	70.00	Ofloren	Indoco	186
Paracetamol Tabs	For Fever, Pain	3.56	7.50	Calpol	GSK	211
Pyrazinamide Tabs. 750 mg	Anti TB.	17.90	65.50	PZA-CIBA	Novartis	366
Roxithromycin Tabs 150 mg	Antibiotic	27.56	59.00	Arbid	Lyka	214

* This work sheet prepared by T.Srikrishna gives estimated prices of a sample range of commonly used drugs currently not under Price Control. The estimated prices are costed using DPCO NPPA norms of conversion, packing and losses.Column 7 gives the extent to which prices in the market are above DPCO norms if the latter were applicable. For example, Amloguard by Pfizer is priced **28.82 times** what would have been its price if it were under price control. Drug prices of leading brands from CIMS, April 2004.

Chapter 10: COSTING AND PRICING OF A DRUG FORMULATION

-T.Srikrishna

We try to explain in this chapter – and hopefully demystify – the costing and pricing of drug formulations. Most formulations sold in the world are in the form of tablets and capsules and therefore we focus here on these. The procedure is however the same for all other presentations of a medicine. We do not discuss the costing of a bulk drug, vaccine, or injectibles here.

Components of Cost

Components of cost of medicines (that is in this case tablets, capsules, liquids) are:
Raw material costs, manufacturing/conversion costs, packing costs, quality control/testing costs, yield/losses, marketing costs that include trade margins, promotional costs, etc.,.

Raw Material Costs

Raw Material Costs include the actual cost of the raw material and other additives added to make the final product. The cost of the active ingredient depends on the actual cost of the raw material and its content in the tablet.

For example tablets of paracetamol/acetaminophen (brand names: Crocin, Metacin) are usually of 500 mg strength. Therefore 1 kg has enough raw material for a maximum of 2000 tablets: that is a maximum of 2000 paracetamol tablets of 500 mg each can be manufactured. Let us say the price of paracetamol bulk drug (that is the white powder) is Rs 180 per kg including all taxes. This means the cost of paracetamol raw material per tablet is Rs 0.09, that is 9 paise. We cannot price it less than 9 paise, unless one wants to make a loss.

Similarly the cost of prednisolone (a steroid) is Rs 35,000 per kg. For a 5 mg tablet the cost of prednisolone raw material is Re 0.175, i.e., 17.5 paise.

There are fluctuations in the price of raw material - sometimes small and sometimes huge. When the fluctuation is large it becomes necessary to vary the price of the medicines. For example, some years back, isoniazid (an important drug in controlling TB) was available at around Rs 375 per kg. As of writing, the price is around Rs 700 per kg. Paracetamol similarly has seen an increase of around Rs 30 per kg in its price. Which in turn means an increase the price to the end consumer - if you want to make the same level of profit.

The component of the cost of additives is small in the case of tablets and capsules. In the case of syrups, the component of the actual raw material (active ingredient) is low. The cost of additives, the packing, the bottle, the carton and the sugar, are much more than the cost of the actual active ingredient in the case of syrups. Which is one good reason to discourage use of syrups beyond very small children.

Once we know the actual cost of the active ingredient in the medicine we get a fairly good idea of the actual cost of manufacturing the medicine, as we shall see later.

Manufacturing/Conversion Costs

These costs include the cost of labour, electricity, water, etc., needed to manufacture the medicines. We consider these to be fixed costs to a very large extent. (The operative word here is very large extent). These costs do not vary much on the production quantities for a given manufacturing setup.

So higher production or better capacity utilisation means that the component of this cost per unit tablet or capsule comes down because the same costs are allocated on a larger number of products.

Packing Costs

This component of cost is manufacturer dependent. Fancy packing versus utilitarian packing, determines this component of the cost. Packing should be determined, if you want to keep the costs low, by the need to maintain the medicine unaffected by the environment and not so much for being attractive.

Strip packing or blister packing is costlier than bulk packing. The additional cost of blister pack – in the author's experience at LOCOST given current costs of strip packing material like aluminum foils, etc., -- over bulk packing is around Rs 50-100 per 1000 tablets, that is, a strip packed tablet should cost a maximum of 10 paise over the bulk packed one. That is if the bulk pack of paracetamol costs Rs 150 per 1000 tablets the strip pack should not cost more than Rs 2.50 per 10 tablets, i.e., Rs 250 per 1000 tablets.

Laboratory/Quality Control Costs

Like manufacturing costs, these costs too are a fixed cost to a very large extent. Increased efficiency and capacity utilisation bring down the unit cost per tablet or capsule.

There is a wrongly held belief that price is related to quality. This is true only to a certain extent. As we mentioned earlier, these costs for quality control are fixed and do not vary much and therefore do not contribute very much to the cost of the medicines.

Yield/Loss

There are manufacturing losses incurred during the process. There are also samples to be drawn for testing, statutory samples to be maintained with the manufacturer during the life of the product. Considering all these, the average yield in the case of tablets or capsules is around 98 %. In the case of syrups the losses are slightly higher - around 5 %, i.e., the yield is 95 %. These losses will also have to be factored in while calculating costs.

Marketing/Distribution Costs

These costs add up to a substantial portion of the costs. These include margins given to wholesalers and retailers. The costs of the medical representatives, the gifts and free samples given to the doctors, all add up to the cost of the medicine.

The usual margins for top-selling brands are supposed to be: 2 to 5 % for the wholesalers and 8 to 16 % for the retailers. In many cases as in generics, especially branded generics, the margins are much higher. As shown in the other chapters of this book, the pricing of many top-selling brands reveals that the bare ex-factory costs as calculated by the procedure indicated in this chapter and the retail price is of the order of even 2000 to 5000 percent. This means actually a lot more margins are made and shared down the trading chain. Similarly in case of OTC products, which involve a push by the chemist, the margins are much much higher. **Please note that manufacturing costs (that is converting the powder to the tablet form) for costly material like prednisolone, and for one that is much less costly like parcetamol, is about the same.**

Taxes And Excise Duties

After the manufacturer decides on his/her ex-factory price of the medicine, excise duty is levied (some essential drugs are exempt however) when the goods leave the factory premises. This rate varies depending upon the manufacturer. Small-scale units are allowed to pay 9.6 % up to a limit (up

to sale of one crore rupees); and after that it is 16 % whereas other manufacturers are required to pay uniformly 16 %. The Excise Duty component of the cost gets included in the MRP of the medicine along with other costs and margins of profit.

State sales tax is levied at the point of first sale in a state – and hence usually recovered by the manufacturer or his/her agent from a whole saler or a forwarding agent. Other local taxes such as octroi, etc., are collected as applicable. **Tax is not applicable on the MRP** –see box below 'Local Taxes Extra – who benefits, how?' although it is collected by all retail pharmacists as a percentage of the printed MRP (Maximum Retail Price). The sales tax varies from state to state. Not only does the rate vary but also the list of items taxable and items exempt from tax also vary from state to state. This component of the cost of the medicine is not included in the MRP. But the sales tax paid by the first purchaser in the state is collected from the end user –that is the buyer at the retail pharmacy.

BOX

'Local Taxes Extra' – who benefits, how?

Assuming that, for sale of medicines, wholesaler's margin is 10% and retailer's margin is 20% and 'x' is the amount of local taxes (sales tax, octroi, etc.), say 8.8 %.

Purchase Price	**Price at each trading chain**	**Equals**	**Rs**
	Manufacturer's Price, ex-factory	= Rs 100	100.0
	Manufacturer's Price to Wholesaler	= Rs.100 + x	108.8
108.8	Wholesaler's Price to Retailer	= Rs. (100+10%) + x	118.8
118.8	Retailer's Price to Consumer	= Rs. (100+30%) + x	138.8

Note: 'x' stands for sales tax and other local levies. Excise duty is paid separately by the manufacturer on his ex-factory price; and in this example is included in the manufacturer's selling price of Rs 100/- to the wholesaler.

Sales tax is changed by the manufacturer to the wholesaler (first sale) and paid to the government. Subsequently, price at other stages of the trade chain becomes inclusive of sales tax amount (already charged by the manufacturer). But it is not charged again as Sales Tax and therefore, its payment to the Govt. does not arise. That is every level of trader from wholesaler to the retail pharmacist passes it down the chain and is ultimately sought to be recovered from the consumer.

If we compare the prices, Rs.108.8, Rs. 118.8, Rs. 138.8, we notice that sales tax amount (Rs.8.8) is added to the price at only one stage. Subsequent price differences are not wholesaler's and retailer's margins.

The mischief is: Retailers calculate 8.8 % on Rs.130 (MRP), that is Rs 11.44, instead of on original manufacturer's price of Rs. 100; 8.8 % on Rs 100 is of course Rs 8.80. Additional (illegal collection by the retailer if you may) is Rs 11.44 less Rs 8.80 = Rs 2.64 which is not remitted to the government. This is because sales tax is always levied at the first point of sale in a state and therefore it is always collected by the manufacturer (or his/her agent or branch office in the state) and remitted to the government. The retailer pays no sales tax normally as he/she is seldom the point of first sale. In effect it is the ultimate end user who pays for the tax levied at the point of first sale. And some as we have seen.

This mess of illegal/unjustified collection can be avoided by putting MRP inclusive of all taxes instead of LTA (local taxes extra). Uniform taxation throughout the country will also help. The difference collected illegally may appear small – that is because in the example we have chosen, the margins from

manufacturer to seller is about 40 percent only. When this difference is about 400 or 2000 percent, then the unjustified collection is substantial.

BOX ENDS

Cost Reduction

Considering the various components, lowering Raw Material costs through efficient purchasing mechanisms like competitive bidding, etc., could reduce costs. As this constitutes the major single component of the cost any reduction in this will reduce the cost and hence the prices of the medicine. We have to keep in mind that the cost of the raw material includes the excise duty and taxes paid for it.

The government has exempted some medicines (like some anti-TB medication from excise duty). A reduction in rates of excise duty and sales tax of the raw materials and/or finished goods could therefore reduce the cost and hence the price of the medicine – that is hoping the manufacturers and the traders pass on the benefits to the customer.

Reduction in production losses and improvement of efficiency and better capacity utilisation would also reduce the costs. However the scope of reduction of costs on this front are limited considering the fact that their component in the total costs is not very large.

Marketing costs, costs of fancy packing etc., could however reduce the prices to a large extent.

Schedule M Implementation and Its Costs Implications

The government has introduced a new schedule in the Drugs and Cosmetics Act - Schedule M to ensure the quality of the medicines manufactured in the country. This schedule lists out various additional measures that need to be taken while producing medicines.

Some of the measures include setting up Air Handling Units in all the departments. The provisions for minimum space requirement and equipment required are stricter than the existing requirements. There are also several documentation and other related requirements not present now. All this involves an additional capital outlay. This will adversely affect the small-scale industries because many of them will not be able to find the money to meet all these requirements. It is a debatable point as to the essentiality of all these requirements.

This additional capital outlay will definitely increase the cost of quality control/quality assurance to a new level. That is, though the cost would not vary with production it will now move up to a new higher level and will remain independent of the production quantities at that level. This will in the final analysis increase the costs of the medicines

Costing of Paracetamol 500 mg Tablets: An Example

These quantities are for a 150,000-tablet batch size. The jargon regarding each component of the cost is explained later below.

COSTING FOR PARACETAMOL TABLETS

	Quantity required per batch in kgs		Value in Rs.
RAW MATERIAL COST - Paracetamol	75.000		13480.00
EXCIPIENT COSTS			1016.00
TOTAL RAW MATERIAL COST[1]		(A)	14496.00
MANUFACTURING COSTS			
Labour Cost			1200.00
Electricity Cost			1500.00
Packing Material Cost			1250.00
Testing Charges			1500.00
TOTAL MANUFACTURING COSTS		(B)	5450.00
TOTAL COST		(A) + (B)	19946.00
TOTAL COST PER 1000 TABS			135.70
Assessable Value			176.40
Excise			12.24
Selling Price			188.64
MRP PER 1000 TABS			234

Raw Material Costs

Each tablet of paracetamol is of 500 mg. Therefore for a batch size of 1,50,000 tablets we would require 75 kg of paracetamol. The calculation is as follows–

$$\frac{500 \text{ mg} \times 1{,}50{,}000 \text{ tablets}}{1000 \text{ mg/gm} \times 1000 \text{ gm/kg}} = 75 \text{ kg}$$

In trade parlance the rate of paracetamol is quoted as 149 + + which means the cost of is Rs 149 per kg + Excise Duty (16 %) + Central Sales Tax (4 %). This works out to Rs 179.75 per kg.

The effective cost for 75 kg is Rs 179.75 / kg x 75 kg = Rs 13481.25 say Rs 13480.

Cost of Excipients

The quantities of additives (excipients) needed for a batch of paracetamol tablets are shown below. The quantities multiplied by their rates will give us the cost of excipients.

[1] That is the total Raw Material Cost per 1000 tablets = Rs 14,496 / 150 = Rs 96.64.

Name of Excipient	Quantity (in kgs)	Rate (Rs per kg)	Value (Rs.)
Maize Starch	7.800	20.75	161.85
Gelatin	3.000	235.00	705.00
Glycerin	1.200	87.50	105.00
Talcum	0.600	13.00	7.80
Mag Stearate	0.300	65.00	19.50
Sod. Starch Glycolate	0.300	56.00	16.80
Total Cost of Excipients			**1015.95**

Therefore the total cost of excipients is Rs 1015.95 – Let us say Rs 1016.00.

Manufacturing Costs

Labour Cost

This is calculated based on the number of person days required to manufacture a batch, i.e., the summation of number of persons required for each operation multiplied by the time required for that operation over all operations.

For example, granulation process usually takes half a day per batch with two persons involved.
Sieving, comminuting and lubrication usually takes half a day per batch and involves two persons.
Time taken for tablet compression is machine and tablet related. There are fast machines, slow machines and selection of a particular machine is dependent on the nature, size and shape of tablet being manufactured. At LOCOST, where the author works, a batch of paracetamol of 1,50,000 tablets takes a day and a half (this includes setting the machine and cleaning after the batch is processed) and one operator is needed to run the machine.

Packing is labour intensive for strip packing. For a batch of 1,50,000 tablets approximately 6 people are needed for 4 hours for packing the strips in cartons. Another two are needed to run the machine for one and a half days.

Bulk packing of 1,50,000 tablets of paracetamol would need 4 persons for half a day.

The costing shown above is for bulk packing of tablets. So the total labour cost would be –

2 x 0.5 + 2 x 0.5 + 1 x 1.5 + 4 x 0.5 = 5.5 person days so let us say 6 person days per batch. If we assume a rate of Rs 200 per person per day labour cost would work out to Rs 1200 per batch.

Electricity Costs

Each tablet goes through certain manufacturing operations. Some of the common ones are:
Mixing, Granulation, Drying, Sieving and Comminuting, Tabletting, Packing, Coating (in case of coated tablets).

All tablets do not go through all these operations. The operations are chosen depending upon the nature of the material being tabletted. One particular machine and sometimes two machines do each operation.
To calculate the electricity cost for each operation one considers the time taken for each operation, the machine used, the electricity power required to run that machine. The average cost of electricity per month is calculated. The average number of hours each machine runs in a month is also determined based on historical data. These two sets of data will give us the cost of running each

machine per hour. This is then used to determine the electricity cost for each batch depending upon the machines used.

At LOCOST we have calculated that:
mixing + granulation + comminuting/sieving + drying costs Rs 1100 per batch
Tabletting costs Rs 275 of electricity per 100,000 tablets.
The electricity costs for bulk packing of tablets is negligible.
i.e., for 1.5 lakh tablets the cost is Rs 1100 + Rs 275 x 1.5 = Rs 1512.50, say, Rs 1500.

Packing Material Cost

Most of our products are bulk packed so we have shown the costs for bulk packing.
The jar we pack paracetamol tablets costs us Rs 7.50 per jar. Therefore for 150 jars the cost is Rs 150 x 7.50 = Rs 1125.
The cost of labels is Rs 0.25 x 300 = Rs 75
The approximate cost of the PP (polypropylene) bags used for packing is Rs 50.
Thus the total packing cost is Rs 1125 + 75 + 50 = Rs 1250.

Testing Charges

This includes the total quality control lab expenses, i.e., chemicals, consumable materials, salary of staff, etc. This is an average cost of the total expenses for the year divided by the number of finished goods batches tested. Though the tests include raw materials tested, excipients tested, on process tests and the finished goods tested, the cost is allocated only to the finished goods.

On an average the testing per batch of finished goods costs Rs 1500 per batch.

Total Cost

The total cost is the sum of the Raw Material Cost and the Manufacturing Costs, i.e.,
Rs 14496 + Rs 5450 = Rs 19946

To calculate the total cost per 1000 tablets we divide the total cost by the batch size and also factor in the production losses. In this case the production losses are 2 % and therefore the total cost would increase to that extent.

Therefore the cost per 1000 tablets is $\frac{\text{Rs } 19946 \times 100 \times 1000}{1{,}50{,}000 \times (100 - 2)} = \text{Rs } 135.70$

That is for a raw material cost (see footnote 1) of Rs 96.64, the value added is Rs 135.70. This is approximately the value added for all (uncoated) tablets and can be used as a thumb rule to calculate ex-factory costs of various items, the raw material prices are usually available in the trade journals like *Chemical Weekly*, etc.

Assessable Value

Assessable value is the net realisable value for LOCOST. Net realisable value is decided by how much we want to price it at the first point of sale (to the wholesaler usually). This includes the margin, a polite word for gross profit.

Excise Duty

Excise Duty is calculated on the assessable value. It is usually 16 % but small-scale industries have a concessional rate of 9.6 % up to a sale of Rs 1 crore after which they have to pay 16 %.

In the case of excise duty if you see it does not work out to either 16 % or 9.6 % because excise duty is paid only on the *value added.* That is, excise duty paid for all the inputs can be subtracted from the total excise duty payable and hence the figure is lower.

LOCOST selling price works out to Rs 188.64, i.e., say Rs 190 per 1000 tablets for bulk packing.

NPPA and DPCO Norms

The NPPA (National Pharmaceutical Pricing Authority) is the implementing agency of the Drug Prices Control Order (DPCO).

The retail price for price-controlled drugs is to be calculated by the government on the basis of the following formula given by the DPCO –

R.P = (M.C + C.C + P.M + P.C) X (1 + MAPE/100) +ED.

Where –
R.P means retail price that is the price printed on the pack.

M.C means Material Cost and includes the cost of drugs and other additives used including overages, if any, plus process loss thereon.

C.C. means Conversion Cost worked out in accordance with established procedures of costing.

P.M. means Cost of Packing Material used in the packing of concerned medicine including process loss.

P.C. means Packing Charges worked out in accordance with established procedures of costing.

MAPE (Maximum Allowable Post Manufacturing Expenses) means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed 100 % for indigenously manufactured scheduled formulations *under price control.* MAPE for decontrolled drugs is left to the manufacturer's choice.

ED means Excise Duty.

M.C, C.C., P.M. and P.C. are fixed by the NPPA as a norm every year by notification in the Official Gazette.

The latest NPPA norms, as of September 2004, for tablets of a typical paracetamol shape and size are:

Conversion Cost: Rs 13.75 per 1000 Tablets
Packing Charges: Rs 2.04 per 1000 Tablets
Process Loss:
Raw Material – 3 %
Packing Material – 3 %
PM Cost: Rs 2.61 + 0.006 x 900 = 8.01

Therefore the calculation of Retail Price is as follows –

$$\left(\text{Rs } \frac{135.70}{0.97} + 13.75 + 2.04 + \frac{8.01}{0.97}\right) \times (1+100/100) =$$

(139.90 + 13.75 + 2.04 + 8.25) x 2 = 327.88 + ED

Assuming an excise duty similar to the calculation above, i.e., Rs 12.24 per 1000 tablets –

The maximum retail price is Rs 327.88 + Rs 12.24 = Rs 340.12

This as you would notice is way above the maximum retail price calculated from LOCOST's actual experience; which only means that the norms of NPPA/DPCO are already liberal. .

What is MODVAT?

MODVAT, or modified value added tax, is a taxation system that avoids tax on tax. The tax is only on the value addition done. At present excise duty is paid as MODVAT. It works this way:

The excise duty for the finished goods is calculated at the specified rate and excise duty paid for the raw materials used is deducted. The balance is what is payable by the manufacturer.

As mentioned earlier the prices of raw material are quoted in the trade parlance as price + + (to be read as say Rs 120 plus plus). For example the price of paracetamol is Rs 149 + +. This means the price of Raw Material per kg is: Rs 149 + 16 % Excise Duty + Sales Tax.

Assuming a sales tax rate of 4 % on raw material, the cost of paracetamol works out to Rs 179.75 per kg. The excise duty is Rs 23.84 per kg

The calculation to determine the excise duty payable on the paracetamol is given below –

From 1 kg of paracetamol we get 2000 tablets of paracetamol 500 mg.

Assessable value of paracetamol tablets in the above example is: Rs 176.40
Excise duty payable per 1000 tablets at the rate of 9.6 % is: Rs 16.93.
For 2000 tablets the excise duty payable is Rs 16.93 x 2 = Rs 33.86.
Deduct the excise duty paid (on 1 kg raw material): Rs 23.84.
Total excise duty payable: (Rs 33.86 – Rs 23.84) = Rs 10.02.

This figure is slightly different from the one above because we have made corrections for losses, the rate is not uniform @ 9.6 % for the whole year so we have taken a weighted average of the rate of excise duty.

Sales tax is **NOT** calculated as above. In the case of sales tax, rebate for tax paid earlier is not given and the tax is calculated on the sales value. There is a proposal for introducing VAT in the case of sales tax. It was to be introduced in April 2004 but has been postponed. If introduced the calculation will be the same as in the case of Excise Duty. The tax incidence will be less and hopefully the trade will pass it on to the consumer.

CHAPTER 11

ANOMALIES IN DRUG PRICING and SALE OF DRUGS:

A look at drug prices in a neighbouring country and an analysis of what sells the most in India

Charity begins Abroad!

Indian companies - and sometimes the same Indian companies who violate the drug price control order at home - sell medicines at dramatically lower prices in neighbouring countries. See for example at No 6, the prices of Aceten (Captopril) marketed by Tridoss in the Table 1 below. This is the same company, which has a near monopoly over the market for captopril in India, and which violates the National Pharmaceutical pricing Authority's ceiling price of Rs. 0.84 (exclusive of excise and local taxes) at home. It has no problems in selling the very drug for Indian Rs. 0.35 (that is what Rs. 0.79 in Sri lanka would translate into) in Sri Lanka when faced with competition.

Table 1: Variation in Prices of Drugs Manufactured by Indian Drug Companies: Indian Retail Market and Sri Lankan and South Asian Retail Market

(One SL Rupee = 0.4570 Indian Rupee)

Sl. No	Generic name, strength, dosage form	Unit Price in INR of Most Sold Equivalent in India	Price in Sri Lanka In SLR of Lowest Priced Equivalent	Remarks
1.	Acyclovir 200 mg tabs	Rs. 5.45 Acivir (Cipla) Rs 5.80 Cyclovir (Cadila)	Rs. 4.42 Cyclovir (Cadila)	Sri Lankan price is 37 % of Indian Acivir. The most selling drug in Sri Lankan is also Cyclovir. Cadila sells in the Sri Lankan market at ~ 34 % of its Indian retail market price.
2.	Amitryptiline 25 mg tabs	Rs. 1.79 Tryptomer (Merind)	Rs. 0.30 MSJ, Sri Lanka	Sri Lankan price is 8 % of the Indian equivalent.
3.	Amoxicillin 250 mg caps	Rs. 4.00 Mox (Ranbaxy)	Rs. 1.69 SPMC, Sri Lanka	Sri Lankan price is ~19 % of Indian
4.	Atenolol 50 mg tabs	Rs. 2.21 Tenormin (Nicholas Piramal)	Rs.0.71 Generic of Kopran, India	Sri Lankan price is ~ 15 % of Indian. The most selling drug in Sri Lanka is Kopran's generic Atenolol.
5.	Beclomethasone inhaler 50 mcg/dose	Rs.0.70 per dose Beclate (Cipla)	Rs. 1.795 per dose Beclate (Cipla)	Sri Lankan price is 14 % greater than that in India.
6.	Captopril 25 mg tabs	Rs.3.50 Aceten (Tridoss, formerly the brand was marketed in India by	Rs.0.79 Aceten, Wockhardt, India	Sri Lankan price is ~ 10 % of Indian. The most selling drug in Sri Lankan is Aceten of Indian origin and is the same drug which is nearly 10 times costlier in India

		Wockhardt)		
7.	Carbamazepine 200 mg tabs	Rs. 1.62 Tegrital (Novartis)	1.38 SPMC, Sri Lanka	Sri Lankan price is ~ 38 % of Indian
8.	Ceftriaxone 1 g inj.	Rs. 95.52 Monocef (Aristo)	Rs. 134 Tabros, Pakistan	Sri Lankan price is 63 % of Indian
9.	Ciprofloxacin 500 mg tabs	Rs. 8.40 Cifran (Ranbaxy)	Rs. 6.68 Ciproleb, Leben, India	Sri Lankan price is ~ 36 % of Indian The most selling drug in Sri Lanka is Ciproleb of Indian origin.
10.	Cotrimoxazole paed suspension (8+40) mg/ml	Rs. 0.20 Septran (GSK)	Rs. 0.508 Eros, India	Sri Lankan price is approx the same as the Indian. The most selling drug in Sri Lanka is of Indian origin
11.	Diazepam 5 mg tabs	Rs. 1.40 Calmpose (Ranbaxy)	Rs. 0.07 MSJ, Sri Lanka	Sri Lankan price is 2 % of Indian
12.	Diclofenac 50 mg tabs	Rs. 1.51 Voveran (Novartis}	Rs. 0.51 Neodol, India	Sri Lankan price is 15 % of the Indian and the most selling in SL is of Neodol, India. .
13.	Fluconazole 200 mg tabs	Rs. 42.28 Zocon (FDC)	Rs. 84.51 Forcan	Sri Lankan price is ~ same as that of the Indian one.
13.	Fluoxetine 20 mg caps	Rs. 2.70 Fludac (Cadila Pharma)	Rs.2.16 Dawnex	Sri Lankan is 44 % of Indian price.
14.	Fluphenazine decanoate 25mg/ml inj.	Rs. 26.90 Prolinate (Sun Pharma)	Rs. 34.31 Deca, Atlantic (Thailand)	Sri Lankan is 57 % of Indian price.
15.	Glibenclamide 5 mg tabs	Rs. 0.66 Daonil (Aventis)	Rs. 0.16 MSJ, SL	Sri Lankan is 11 % of Indian price
16.	Hydrochlorthiazide 25 mg tabs	Rs. 1.00 Hydrazid (Cipla)	Rs. 0.16 MSJ, SL	Sri Lankan price is 7 % of Indian price
17.	Losartan 50 mg	Rs. 4.40 Losar (Unisearch)	Rs. 5.58 Zaart (Cipla, India)	Sri Lankan price is 57 % of Indian price. The most selling drug in Sri Lankan is of Cipla, India. .
18.	Lovastatin 20 mg tabs	Rs. 10.57 Rovacor (Ranbaxy)	Rs. 8.90 Lovolip	Sri Lankan price is 38 % of Indian price.
19.	Metformin 500 mg tabs	Rs. 0.73 Glycomet (USV)	Rs. 0.35 Bal, India	Sri Lankan price is 21 % of Indian price. The most selling drug in Sri Lankan is of Bal, India.
20.	Nifedipine retard 20 mg tabs	Rs. 1.24 Nicardia-R (Unique)	Rs. 1.05 Nifelat	Sri Lankan price is 43% of Indian price.
21.	Omeprazole 20 mg tabs	Rs. 3.98 Omez (Dr. Reddy's)	Rs. 1.57 Belco, India	Sri Lankan price is 18 % of Indian price. The most selling drug in Sri Lankan is of Belco, India.
22.	Phenytoin 100 mg	Rs. 1.19 Dilantin (Pfizer)	Rs. 0.61	Sri Lankan price is 23 % of Indian price.
23.	Ranitidine	Rs. 0.72 Rantac (Unique)	Rs.1.57 Neotrax	Sri Lankan price is approx. the same as the Indian.
24.	Salbutamol inhaler 100 mcg per dose	Rs. 0.38 Asthalin (Cipla)	Rs. 0.895 Asthalin (Cipla)	Sri Lankan price is approx. the same as the Indian. The most selling inhaler for the drug in Sri Lanka is Asthalin of Cipla.

*(*Source: Papers on country prices of key drugs presented at the WHO SEAR Pharm Forum and available in: *A Report on Medicine Prices in SEA Region*, December 22, 2003, WHO, SEAR, India*)*

In 5/24 (to be read as 5 out of 24) medicines the Sri Lankan price was more than the Indian price. In 4/5 of these medicines the manufacturer was from India. The maximum difference was 25% more than the Indian price and the minimum difference was 10%.

In 19/24 medicines (nearly 80%) the Sri Lankan price was lower than the Indian retail price. The maximum difference between Sri Lankan and Indian prices of most sold drugs was of the Sri Lankan drug being 98% lesser than the Indian price and the minimum difference was 30% less than the Indian price. In 8/19 instances of lesser prices of medicines the manufacturers were from India. In one instance the same drug (Captopril) manufactured by the same company was 10 times cheaper in Sri Lanka than in India.

Drug prices in Sri Lanka are lower *for the consumer* probably because there generic drugs compete with the branded drugs for price in the retail market, and because the State (through SPC and STC which are parastatal organisations) itself runs fair price shops, where good quality generic/branded generics drugs are available at a lower price. And since the State seems a major player in the provision of services and also a major purchaser of drugs through worldwide tenders, the drug prices of top selling generics and /or branded generics are quite low compared to India. In India most prescriptions are for branded drugs and state intervention in manufacture and marketing of drugs is minimal. The other point to be noted in the above is that the Indian prices are net of taxes collected from the consumer. In Sri Lanka there are no taxes to be paid by the user at the point of purchase. So the differences between Indian and Sri Lankan price would be even more than shown in the above table. Also the Sri Lankan prices also include trade commission which means they would have been sold at even less by the manufacturers, many of whom as we have seen are of Indian origin. Competition works more apparently in Sri Lanka in the sense that the most-selling drugs are the lowest priced in many of the cases cited above; which is unlike the situation prevailing in India where the most-priced is also the most-selling in many a drug. However we submit this matter needs further investigation.

What has the Indian public gained in terms of affordable prices by a strong indigenous pharma manufacturing sector? What does it matter to the poor person who cannot afford medicines but if India's pharma stocks are doing well otherwise? Sri Lanka has a better health status with almost no domestic pharma industry as compared to India.

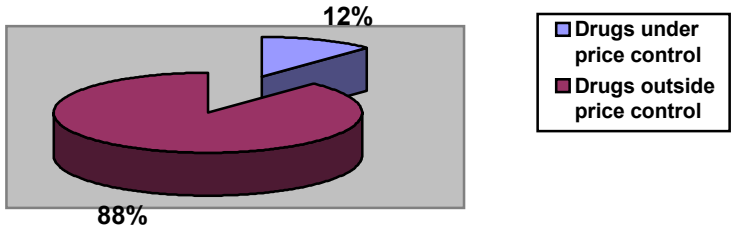
We submit that if India's Central and State Governments buys drugs through open, rigorous tender and sets up retail pharmacy shops, probably quality drugs would be available at much lower prices than at present (as at the time of writing, the Tamil Nadu Government through the TNMSC is planning to do some such thing for vaccines to be sold in the retail for the general public.).

Top 300 Drugs in India: A Brief Analysis

We now present an analysis of the top-selling 300 drugs of India accounting for Rs 19,000 crores sales in India. This analysis of the Indian market is based on the October 2003 data of ORG-Nielsen. This data is collected from a sample of around 280 outlets in India and is based on data from wholesale dealer's sales to retailers. It is not based on retail sales. It is indicative, of market trends in general. However in view of the sample taken and the exclusion of institutional sales, it is likely to be an underestimate of the total volume of sales.

This analysis of the top-selling brands, along with the analysis of the variation in drug retail prices already discussed gives us some insights into the nature of the Indian drug market.

The Indian drug market: Free or regulated?
Data on top selling 300 brands(ORG-Nielsen,Oct2003)



The sales from 300 brands alone are huge and put the government estimates of the sales of the pharmaceutical sector into question. The estimates for the total turnover of the pharmaceutical sector are Rs 40,000 crores (source: pharmabiz.com). The government quotes lower figures. The total Moving Annual Total of from the retail sales of 300 brands alone (there are more than 20,000 formulations in the market) is a whopping Rs 18,000 crores. This figure of Rs.18,000 crores would only be a part of the total sales. The final figure of total sales does not take into account institutional and governmental purchases, which would also be of very considerable magnitude. Some industry estimates put the figure to Rs 40,000 crores (for instance www.pharmabiz.com editorial, dated June 20, 2001: "A Rs. 40,000 crore industry")

Top 300 Brands and their Relation to the National Essential Medicines List

The National Essential Medicines List (NEML) which has been modeled on the WHO Model List of Essential Medicines has been prepared twice, once in 1996 and another in 2003. The concept of essential medicines is now widely accepted as a pragmatic approach to providing the best of evidence-based and cost-effective healthcare.

Essential medicines are those medicines that satisfy the priority health care needs of the population. They are selected with due regard to their public health relevance, evidence of safety and efficacy, and comparative cost-effectiveness. The essential medicines represent the best balance of quality, safety, efficacy, and cost. There are a total of 354 drugs in the National Essential Medicines List, which are adequate to take care of the majority of the health needs of the population during outpatient or inpatient care.

If we examine the list of top 300 brands (as per ORG-Nielsen Oct 2003, see Table 8 for a partial list), we find that only 115 brands are of drugs that are mentioned in the National Essential Medicines List (NEML) 2003, i.e., only 38% of brands of the top selling ones are of drugs mentioned in the NEML, the other 62% are of drugs which do not find mention in the NEML. Of these 62% brands comprise drugs that are higher priced alternatives without a clear therapeutic advantage, and many drugs that are unnecessary, irrational and even hazardous. The number of drugs represented by these 115 brands is only 68.

That means the majority of the top selling brands are of drugs which are outside the National Essential Medicines List, which means that the majority of the drugs which are the most cost-effective for the treatment of priority health needs of the people are not the ones which are selling the most.

A dramatic illustration of the lack of public health relevance of these top-selling preparations is the case of preparations for iron deficiency anemia, which is one of India's most prevalent public health problems.

There is not a single preparation in the top 300, which has the ingredients for an anemia preparation as mentioned in the National Essential Medicines List.

The top selling preparation (Dexorange) is patently irrational (see box on Dexorange below), while others contain substances which are not required (e.g. in Fefol-Z), and which can in fact impair iron absorption.

The mere inclusion of a drug in the National Essential Medicines List does not translate into affordability for the patient, because most of the drugs included in the NEML, are outside price control. Even when the drug is under National Essential Medicines List because of the lack of regulation over drug prices, it is often the costlier version that sells more:

For example, Ciprofloxacin is sold by Ranbaxy at Rs.8.96 a tablet. Yet the cheapest brand of Ciprofloxacin at Rs.2.90 does not sell as much (other examples are given in Chapters 1, 2, etc.).

Top-Selling Drugs Outside the NEML

These are of diverse types and include:

- higher priced brand of either the same drug or a higher priced alternative to a lower cost essential drug.
- irrational drugs and irrational combinations of antibiotics, vitamins, analgesics which include unsafe and hazardous drugs.

Examples abound in this regard:

- Cifran brand of ciprofloxacin is the largest selling antibiotic, whereas it is the costliest among the ciprofloxacins. Other brands of ciprofloxacin, e.g., Zoxan which are 3 times cheaper sells 5 times lesser than Cifran (see Table 1).

- Ramipril is an angiotensin converting enzyme inhibitor like enalapril. It has no therapeutic advantage over enalapril, and is costlier. Enalapril is mentioned in both the National and the WHO list of essential medicines as being representative of the class of ACE inhibitors, while ramipril has not been. Yet it sells more than enalapril (see Table 2).

- Penicillins including amoxycillin, ampicillin are effective antibiotics for a variety of infections Oral cephalosporins are to be used in certain situations only, and mainly when it is not possible to administer oral penicillins because of penicillin allergy. Yet according to the sales figures brands of cephalosporins (phexin, sporidex) clearly outperform penicillins, which indicates inappropriate use. The indications for

erythromycin are similarly limited. However the sales figure for erythomycin is also higher than of penicillins.

This is another area of concern in the Indian drug industry. Irrational combinations of drugs, which only add cost but no therapeutic value, are touted as effective remedies and promoted aggressively.

Irrational Drugs of No Therapeutic Value in the Top 300

Consider the following:

- Irrational drugs like Electral, or drugs which are used irrationally like Evion, Glucon-D, Deca-durabolin are top selling drugs. Protein products are irrationally prescribed and irrationally priced.
- Irrational combinations of vitamins, minerals, and other ingredients including ginseng (which has supposedly aphrodisiac properties), or even an outmoded and dangerous ingredient like animal hemoglobin from slaughterhouse blood, fresh liver extract, are passed off as tonics, haematinics, and food supplements to a gullible population via the medium of obliging doctors. Most of these preparations would be hard to find in any pharmacoepia in the world, but the drug regulatory authorities do not find anything wrong in approving their manufacture. Examples include Revital, elixir Neogadine, hepatoglobins, etc. (see also the box 'Banning of Liver Extract' below and the box on Dexorange below.).
- Irrational combinations of antibiotics: the commonest being ampicillin+cloxacillin which is widely used inappropriately.

Dexorange: top selling anemia preparation which used to contain hemoglobin from animal blood extracts against all principles of pharmacology

An outstanding example of a patently irrational drug is of Dexorange. This formulation is used for treatment of one of the most common and serious health problems of people, anemia. It is the top selling preparation with a Moving Annual Total in retail sales of Rs. 57 crores. Its overall rank in the top 300 brands is No 16 and it outperforms some of the rational preparations for treatment of anemia which do not even figure in the top 300 brands. Till 2000, this company for over a decade and a half was adding minute amounts of hemoglobin obtained from slaughterhouse under unhygienic conditions to its even otherwise irrational formulation of iron.

The amount of hemoglobin added to the preparation was such as to provide a meager additional 2-3 mg of iron per 15 ml.

The addition of hemoglobin of animal origin to an iron preparation is without parallel in the pharmaceutical sector worldwide. No other formulary mentions it, and no other country allows it. How was this preparation passed for marketing in India? The answer is not clear. But it took years for the drug regulatory authorities to notice the irrationality of this top selling preparation and declare a ban on hemoglobin preparations and write:

"hemoglobin obtained from animal blood could be unhygienic and such preparations are needed to be taken in extraordinary high volume to deliver the recommended level of iron in anemic cases and thus lacks therapeutic rationale"

This particular preparation still contains an iron salt, which is less efficiently absorbed, in a concentration that is low, and is still marketed at a price that is extravagant. The cost of treating iron deficiency anemia

with this preparation can be up to Rs. 600 per month, against the cost with a simple iron-folic acid preparation that should cost Rs. 9 per month.

The case of the consistent marketing success of Dexorange is not a mere example but stands as an eloquent testimony to the state of affairs in the pharmaceutical sector, the government and the prescribers, which has put the interests of the voiceless patient/consumer to the background. If after more than a decade during which this company marketed this top-selling preparation adding animal hemoglobin from slaughterhouse blood, the government finds that this addition was not justified, and in fact hazardous, why did it allow a preparation like this to be marketed in the first place? Are the drug regulatory authorities so deficient in scientific understanding that they cannot evaluate a simple preparation for anemia?

Unsafe and Hazardous Drugs Among the Top 300

- Nimesulide, which is one of the best-selling analgesic drugs in India, is not approved in most of the developed world because of its side effects on the liver.
- Preparations containing animal tissue without therapeutic rationale, e.g., hepatoglobine containing fresh liver extract carry the risk of transmitting infection.
- The high sales figures for codeine containing cough syrups are a matter for concern. Both Corex (the no.1 brand in the country with sales of Rs 88 crores) and Phensedyl (rank 29, sales Rs 47.30 crores). These syrups are widely used especially in the northeast as drugs of addiction because of the presence of codeine. They are also smuggled into neighbouring countries like Bangladesh and Myanmar. Does the abuse of these syrups contribute to their high turnover? In contrast Glycodin contains dextromethorphan that is a safe constitutent. It however does not sell as much (rank 259, sales Rs 13.15 crores).

BANNING OF LIVER EXTRACT

P A Francis

A large number of pharmaceutical products with poor rationality profiles are being manufactured and marketed by drug companies in India today. Most of them are fixed dose combinations of drugs and vitamin preparations. No control on their growth has been achieved despite frequent regulatory interventions. One such controversial preparation is the brands containing crude animal liver extracts with a few other ingredients for the treatment of megaloblastic anemia. These formulations have been found to be carrying infective diseases from animals to humans besides causing allergic reactions as they are containing biological products. Currently there are six leading brands of liver extract formulations available in the market for the treatment of anemia. These are Livogen, Ibberol, Plastules B12,RB Tone, Heptaglobine and Hep-Forte. Recent medical studies conducted in India and abroad have questioned the relevance of the continuing use of anti-anemic preparations containing multiple ingredients like liver, iron, folic acid, vitamin B 12, copper, manganese, etc. Some of these ingredients are unnecessary, wasteful and only increase the cost of therapy and risk of infection, the studies have pointed out. But none of the pharma companies had taken any steps to withdraw the liver extract from their products or reformulate them although the use of liver extract has been banned in several countries long ago.

The need to ban the use of liver extracts in drug preparation was first raised by Pharmabiz.com in April 2001. The issue was subsequently taken up by Ahmedabad-based Consumer Education Research Centre with DCGI. But no serious action was initiated by the Drug Controller General of India in this regard. DCGI is reported to be now moving to prohibit the use of liver extracts. A circular is expected to be issued in this regard asking the pharma companies to replace liver extract with pure Vitamin B12. Merck, the leading player in this segment, meanwhile, has decided to withdraw liver extract from its brand, Livogen. Liver extract has been the key ingredient of Livogen tablet and the tonic marketed by the company. The decision of the company is in the wake of its acceptance of the fact that this ingredient has no place in modern therapy as it is unsafe and irrational. Liver extracts used to be the only option before the development of folic acid and vitamin B12 in pure form. But the drug companies have been avoiding use of Vitamin B12 in place of liver extracts despite its abundant availability. Reluctance of the drug companies is mainly on account of the cost factor. Regulatory authorities should know that resistance of pharma companies to recall an established product or change the composition of a well known brand do cause a lot of damage to the public. In matters like this, a faster regulatory initiative is called for.

Source: Pharmabiz, June 19, 2002[1]

[1] Reproduced with permission.

Preponderance of Combinations Among the Top 300

A significant number of the top selling formulations are combinations of drugs, rather than single ingredients. In fact there are 118 combinations in the list of 300. The majority of the combinations are irrational. Only around 20 of these combinations are rational, the rest are combinations, which lack any therapeutic rationale for being combined.

Abundance of Nimesulide Formulations

"...200 nimesulide formulations marketed in the country are without the approval of Drug Controller General of India. Out of these 200 products, 70 are nimesulide suspensions and the remaining 130 are fixed dose combinations of nimesulide with a number of other drugs. Combinations of nimesulide and paracetamol, numbering 50, are the largest segment in this group. Combinations of nimesulide and two muscle relaxants namely tizanidine and serratiopeptidase with as many as 52 brands are the other two major combination groups. Top selling brands in all the three categories are being marketed by major pharmaceutical companies in the country. What is astonishing here is that so many irrational combinations of nimesulide are being marketed in the country at a time the very safety of this drug is under a cloud."[2] ...
Nise (Nimesulide) is the top selling analgesic in India and there are a number of me-too irrational combination formulations of Nimesulide when the drug itself has been discarded in several countries on safety concerns[3].

Source: P A Francis: "Vicious Circle of Combinations", *Pharmabiz.com*

In conclusion:

The pattern of production and the pattern of sales do not adequately reflect the real health needs of the people. There is overrepresentation of costly antibiotics, irrational multivitamin preparations, cough syrups, ineffective haematinics, pain balms, rather than cost-effective drugs of real therapeutic value.

The sales figures reflect the fact that in India, drugs which are not considered essential sell more than rational and essential drugs, that costlier drugs most often sell more than cheaper alternatives (even those made by well known manufacturers), and downright irrational and hazardous drugs are among the top sellers. The majority of sales are coming from the sales of drugs not considered relevant by experts for inclusion into an essential medicines list, and not considered important by the government for regulation of their price.

The analysis of the top 300 brands suggests that the Indian doctors are prescribing drugs without adequate concern for evidence of their efficacy, safety, and cost. This is because of the poor access to unbiased information on drugs for doctors in India compounded by the aggressive and misleading drug promotion by the drug industry. The result is increased health care costs for the patients, irrational use of drugs, exposure of patients to the risks of unsafe drugs.

[2] Source: P A Francis: "Vicious Circle of Combinations", *Pharmabiz.com*. Reproduced with permission.
[3] 'Nimesulide: Drug linked to child deaths is still available in India' *BMJ* 2003; 326:70 (11 January)

Appendices[4]

Table 1: Costliest among the same drug, sells more and much more

Drug	Brand/Manu-facturer	Cost per tablet.	Rank in top 300	Moving annual total (in rupees crores)
Ciprofloxacin 500 mg	Cifran/Ranbaxy	Rs. 8.96	Rank 7	Rs. 62.70
Ciprofloxacin 500 mg	Zoxan/FDC	Rs. 2.9	Rank 284	Rs. 12.37

Table 2:Costlier alternative (not in the essential drugs list) drugs sells more than equally effective drugs, which are essential and cheaper

Drug	Brand/Manufacturer	Cost per unit	Rank in top 300	Moving annual total (rupees crores)	Remarks
Ramipril	Cardace/Aventis	Rs. 7.75 for 5 mg	19	55.31	It has the highest selling ACE inhibitor despite being costlier and having no definite therapeutic advantage over enalapril.
Enalapril	Envas/Cadila	Rs. 1.72 for 5 mg	41	41.07	

Table 3: Hazardous drugs sell more than rational preparations

Drug	Brand/Manufacturer	Cost per tablet.	Rank in top 300	Moving annual total (in rupees crores)	Remarks
Nimesulide	Nise/ Dr. Reddy's	Rs. 2.57	Rank 14	Rs. 58.31	Nimesulide is not approved in the US, UK, and even in Sri Lanka because of adverse effects
Ibuprofen	Brufen/Knoll Pharma	Rs. 0.67	Rank 28	Rs. 25.60	Ibuprofen is approved in all these countries and is safer.

Table 4: Irrational and costlier preparations sell more than rational and less costly preparations

Drug	Brand/ Manu-facturer	Cost (local taxes extra)	Rank in top 300	Moving Annual Total (in rupees	Remarks

[4] All data originally from ORG AC-Nielsen Oct 2003

				crores)	
Dexorange	Franco-Indian	Rs. 46.30 for 200 ml. Rs. 37.30 for 30 tabs.	Rank 16.	Rs. 57.65	Dexorange has the wrong salt(ferric rather than ferrous) in the wrong dose(only 32 mg per 15 ml)in the wrong formulation(why do adults require a syrup?). Till 2000 it contained animal hemoglobin obtained from slaughterhouses, which was irrational and dangerous. Yet it is the highest selling hematinic.
Autrin	Lederle	Rs. 18.32 for 30 tablets	Does not figure in top 300	?	It has therapeutically effective of the right iron salt, yet it sells nowhere as much .

Table 5: Irrational Preparations Sell More Than Rational Preparations

Drug	Brand/Manufacturer	Cost per unit	Rank in top 300	Moving annual turnover (rupees crores)	Remarks
Electral	FDC	11.50 for 35 g sachet	Rank 65	Rs. 31.86	Electral is the highest selling so-called ORS brand in the country. It does not conform to the WHO standards. It has lower sodium level and higher glucose content which has no rationale.
Punarjal, Vitalyte	FDC, Pharmasynth	Rs. 11.20 for a 30 g sachet, Rs. 11.80 for a sachet	Do not figure in the top 300 drugs.		These preparations conform to the WHO standards yet do not sell enough to be in the top 300.

Table 6: Combinations (irrational) that sell more than single ingredient preparation

Drug	Brand/Manufacturer	Rank in top 300	Moving annual total (rupees crores)	Remarks
Ampicillin	Numerous	None. Does not figure in the top 300 drugs	Not known	Ampicillin +Cloxacillin is not mentioned as a standard combination either in the National Essential Medicines List or in the WHO list of Essential Medicines.
Ampicillin+ cloxacillin	Ampoxin Megapen Ampilox Novaclox ,		43.48+34.83+29.22+18.58= 126.11 crores.	The popularity of this unapproved combination is beyond therapeutic rationale

Table 7: Most common and important public health problem of India according to the pharmaceutical industry: Not anemia, but B-complex deficiency!

Brand	Rank in top 300 brands	Moving Annual Total (rupees crores)
Becosules	2	79.74
Revital	27	47.64
Polybion	42	40.85
Zincovit	60	32.26
Cobadex forte	88	26.10
Methycobal	116	21.87
Zincovit	118	21.65
Neogadine	119	21.52
Riconia	125	20.78
R.B. Tone	129	20.21
A to Z	145	19.07
M2tone	157	18.22
Supradyn	221	15.25
Becadexamin	229	14.63
Raricap	239	13.89
Becosules-Z	295	12.03
Optineuron	297	11.97
		437.68*

Table 8: Top-Selling 25 Brands in India as per ORG-Nielsen Retail Audit, Oct 2003

	Brand Name	Uses and Remarks	Moving Annual Total in rupees crores
1	Corex	Cough suppressant. Abused as drug of addiction because of presence of codeine.	88.18
2	Becosules	Multivitamin, unnecessary preparation.	79.74
3	Taxim	Bacterial infections	77.05
4	Voveran	Pain relief	76.14
5	Althrocin	Bacterial infections	68.46
6	Human Mixtard	Diabetes mellitus	63.39
7	Cifran	Bacterial infections including typhoid	62.70
8	Liv-52	Ayurvedic liver preparation	62.67
9	Asthalin	Asthma.	61.76
10	Sporidex	Bacterial infections	61.71
11	Betnesol	Allergy	61.11
12	Zinetac	Dyspepsia, ulcer disease	60.70
13	Neurobion	Irrational Multivitamin preparation	60.27
14	Nise	Hazardous drug for pain relief	58.31
15	Digene	Antacid	57.86

16	Dexorange	Irrational preparation for anemia.	57.65
17	Phexin	Antibiotic for bacterial infection.	57.03
18	Mox	Bacterial infections	56.36
19	Cardace	Hypertension, heart failure, much cheaper alternatives exist	55.31
20	Rabipur	Vaccines against rabies	54.40
21	Omez	Peptic ulcer	53.52
22	Ciplox	Bacterial infections	51.69
23	Combiflam	analgesic combination.	49.02
24	Aten	Hypertension	48.87
25.	Augmentin	Costly antibiotic	48.63

Table 9: Top Selling 10 Categories of Drugs in the Top 300 Brands: Where is the People's Money Going?

Type of drug category	**No. of Brands**	**Moving annual total (in crores of rupees)**	**Remarks:**
1.Anti-infectives	65	1650.02	Most frequently used and abused drugs when antibiotics are given for fever due to viral infections
2.Analgesics	26	705.06	Hazardous analgesics like Nimesulide are one of the top sellers.
3.Endocrine disorders like diabetes mellitus, hormones	25	694.10	
4. Multivitamins and minerals	27	651.29	Contains predominantly non-essential drugs in all kinds of irrational combinations.
5.Drugs for cardiovascular disease	26	601.64	The top selling cardiovascular drug is one that has little therapeutic advantage over less costly alternatives.
6.Drugs for respiratory	21	512.59	Cough syrups sell

system, including cough preparations			more than drugs for asthma.
7.Drugs for gastrointestinal system	20	427.21	Their large scale is also the result of over prescription.
8.Drugs for allergy	10	326.51	
9. Anticonvulsants.	9	221.35	
10.Hematinics	6	128.13	Contains such irrational wonders of the pharmaceutical world as Dexorange (57 crores) which till recently contained animal blood from slaughter houses, Hepatoglobine. etc.

Chapter 12
PREVENTION BETTER THAN CURE?
ISSUES OF CONCERN IN THE PRICING AND MARKETING OF VACCINES IN INDIA

- Anurag Bhargava, Yogesh Jain

Microbes are nothing... the terrain everything.
--Louis Pasteur.

How do you foresee the future of the drug industry?

Drug industries can grow in India faster than anywhere else because of the sheer number of patients here. We can't be proud of this, but that's a fact.

–An interview with Dr. Anji Reddy of Dr. Reddy's Laboratories in the Financial Express, *October 20, 2000*

Background

India offers good 'growth' prospects for the pharmaceutical industry because of the sheer number of patients – the largest number of patients with TB in the world, the second largest number of HIV infected, and a total number of patients with diabetes and hypertension which would be bigger than the population of many large European nations. When it comes to the question of vaccines, the 'prospects' are even better. Drugs are meant for the diseased only to be used when they fall sick, but vaccines are for the healthy who can be injected anytime. With a population of one billion, India offers a very large market for those in the business of making vaccines.

Vaccines are one of the key public health interventions for prevention of disease. Traditionally they have been developed and used for those diseases that are life threatening, or cause significant disease in a large number of people, or are not preventable easily by specific public health interventions in the absence of significant improvements in socio-economic indicators. Thus the classical vaccines against smallpox tetanus, diphtheria, poliomyelitis, pertussis, measles, etc., could achieve if implemented universally the eradication or control of these diseases, even without significant improvements in the socio-economic status of the societies that they were used in.

Lately there has been the development and promotion of vaccines against diseases that are not necessarily life threatening may not affect large numbers of people and importantly could be controlled effectively by public health intervention, which are feasible, and cost effective. The vaccine against chicken pox and the vaccine against hepatitis A are cases in point. These vaccines do fulfill needs of particular individuals, and patients, and thereby represent an advance in medicine. However they cannot be said to be tools of public health, because in the former instance chicken pox with its benign course is not a public health problem, while in the case of hepatitis A, a more cost-effective measure would be provision of safe drinking water.

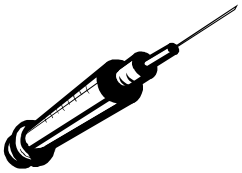
The selling prices of these vaccines as will be seen in this chapter are priced way beyond the means of the common person.

The price per unit of a vaccine or sera is among the highest in any category of drugs in the market except anti-cancer drugs and drugs like streptokinase.

The vaccines against rabies are an obvious example. Dogs in India bite a large number of people and a large number of such people develop rabies in the absence of proper vaccination.

Sera of various kinds are also highly expensive. A poor patient with tetanus, rabid dog bite, or snakebite envenomation may be driven to destitution by the cost of the antisera itself. The cost of anti-D sera for a Rh negative mother carrying a child by a Rh positive father would not allow the majority of such mothers to access this intervention which is so critical to the health of her future children.

Imagine this Scenario



Dhondubai Patil and his wife live in Dharavi, in Mumbai, proudly called Asia's largest slum. They have only 2 children. Dhondubhai is a carpenter, while his wife works as a domestic in the apartments nearby. They get water from a common tap that is perilously close to the open sewage drain. They seek health care from a general practitioner who operates within Dharavi itself. They find the general practitioner telling them increasingly about prevention of diseases by vaccines. A year earlier they were vaccinated against hepatitis B, by the same practitioner who never sterilised his needles earlier, and who was possibly responsible for the prevalence of Hepatitis B in that part of Dharavi. A visit for diarrhoea (which most people in his neighbourhood have had) made them aware of vaccines for typhoid, and hepatitis A, which his GP said he and his family should take. It would cost them Rs. 3000 only, which they said they could not afford. It had been difficult enough spending Rs. 1500 on those five injections to prevent rabies for their son who got bitten by a street dog. And now when their second child has been born the GP insists that in addition to the vaccines supplied by the Government free of charge, they should get their child vaccinated against Hepatitis A, Hepatitis B, hemophilus influenzae B, varicella-zoster, *if they love and care for her.*

The above scenario is not hypothetical, but a potrayal of what is happening in clinics in towns and cities all over India. In recent years the Indian drugs market has seen the introduction of a number of vaccines and sera. Some of these like the safer cell culture based rabies vaccines have filled a lacuna, whereas in the case of some others like the varicella vaccine the justification for their presence is hard to understand. Many diseases that are of public health importance in India lack an effective vaccine: for instance falciparum malaria, tuberculosis, and HIV disease.

Cure better than Prevention?

The emphasis on vaccines to the exclusion and neglect of other public health interventions, their appropriateness for application on a mass basis in the light of the epidemiology of the diseases that they are supposed to protect against, the costs of these vaccines and the government's failure to intervene in the public interest, and the promotional practices of the companies in marketing these vaccines --- are all cause for grave concern.

1. ***The emphasis on vaccines is sidelining other public health interventions that would be far more cost-effective and have lasting value***

   Rather than being a tool of public health to be used judiciously the use of vaccines are in fact undermining the processes of public health. The use of many of these vaccines is a wrong solution based on a wrong diagnosis of the public health problem.

   For example vaccines against hepatitis A, has been developed and are being aggressively promoted. Hepatitis A is usually a mild illness in children and also in adults. The disease is eminently preventable if one could ensure safe drinking water- an intervention that would protect the community from so many other life threatening diseases like typhoid, cholera, gastroenteritis, etc.

What is more rational, equitable, and cost-effective?

Provision of safe drinking water to the community at the cost of a few rupees per head.

OR

Immunisation of the individual against typhoid, hepatitis A, cholera, and yet undiscovered vaccines against the myriad other organisms which cause diarrhoea, jaundice, e.g. Hepatitis E, Esch.coli, etc., at the cost of a few thousands of rupees per head.

2. ***Waiting for vaccines to be developed against TB, malaria, and HIV has become an excuse for not doing what would otherwise be indicated for disease control.***

The epidemiology of communicable diseases has enabled an understanding of the wider determinants of the disease occurrence and its frequency. The control of communicable diseases like TB, malaria and HIV that has been achieved in many parts of the world has been based on this understanding of their epidemiology. Control of TB has involved improvement of nutrition and the social conditions under which people live apart from effective treatment of TB cases. Control of malaria has been achieved by integrated strategies involving vector control, personal protection measures and early treatment. Similarly a HIV/AIDS control strategy has to be multi-pronged.

Instead of an epidemiology based multi-pronged approach, vaccines offer a totally germ-centric approach, which neglects the social, political, demographic, behavioral, and health system-related determinants of the disease.

3. ***How appropriate are these vaccines?***

The appropriateness of some of these vaccines in the Indian scenario is questionable considering the nature of the diseases, the epidemiology of these diseases in India and finally the cost of the vaccines.

Varicella (chickenpox) is widely accepted as an illness that is most often mild, causes an illness of 1-2 weeks, and heals without complications in 99% of those infected. Chickenpox can however cause a more serious illness in those who have immunodeficiency and the need for a vaccine arose because of such patients. The promotion of this vaccine to all is inappropriate as the disease can hardly be called a disease of public health importance[1].

Let us take the case of Hepatitis A, which is of public health importance. It is a viral disease transmitted by faeco-oral route through contaminated food, water, etc. The illness is usually mild and uncomplicated, and the most cost-effective method as mentioned would be supply of potable water, which could take care of a host of pathogens causing diarrhoea.

The company making the vaccine is recommending it to all children above the age of 2 years, and in patients with chronic liver disease. Infection at any age with the Hepatitis A virus results in life-long immunity. This vaccine could be considered for use in all age groups only if we assume that the number of people who get naturally infected is not significant.

However a recent study tells a different tale (see box below).

Trying to Protect the Already Protected: The Scientific Evidence against Vaccination against Hepatitis A to all Children and Adults

A study conducted by the Dept of Gastroenterology and Pathology at All India Institute of Medical Sciences, and published in the Journal of Gastroenterology and Hepatology in 2003, found that 93.2% of the school children between 4-18 years of age had antibodies to HAV in their sera, and 97.6% of patients with chronic liver disease had similar antibodies. The study concluded that mass vaccination is not required in north India because of the presence of protective antibodies against HAV in the majority of the population.

Source: Acharya SK etal. 'Seroepidemiology of hepatitis A virus infection among school children in Delhi and north Indian patients with chronic liver disease: implications for HAV vaccination'. *J Gastroenterol Hepatol*, 2003 July. 18(7): 822-7.

The above study clearly indicates that vaccination for HAV (Hepatitis A Vaccine) would not be warranted in the majority of the population. Its use in a population that already has protective levels of antibodies is like giving a drug that is not indicated in the first place.

[1] The Indian Academy of Pediatrics (IAP) 'opines that varicella vaccine is not recommended for universal immuniza-tion in India at present.' See 'Update on Immunization Policies, Guidelines and Recommendations', *Indian Pediatrics*, 2004, 41:239-244

It constitutes irrational use and a waste of people's precious resources (in this case it constitutes more than a month's income for an average Indian)

The manufacturer may however argue that the presence of past evidence of infection in such a large number of people is evidence enough for the role of the vaccine. But then is vaccinating every child in a household with a vaccine for Rs. 1400 the most cost-effective intervention to prevent HAV?

The Indian Academy of Pediatrics on the Hepatitis A Vaccine

Hepatitis A (HA) vaccine is not recommended for universal immunization in India at present. One has to emphasize the generally benign nature of and rarity of complications with Hepatitis A infection in young children. It may be offered to children from high socio-economic strata of society after explaining the pros and cons to the parents on a one-to-one "named child" basis.

'Update on Immunization Policies, Guidelines and Recommendations',
Indian Pediatrics, 2004, 41:239-244

In developed countries where safe drinking water is assured to the population the use of the hepatitis A vaccines is restricted to use in a few groups at high risk of contracting infection like travelers, personnel with risk of occupational exposure to the virus. To promote this costly vaccine in a country where provision of safe drinking water should be a public health priority is a travesty of the principles of public health.

It may be argued that such a vaccine should be available to those who can afford it, as the above extract quote from the *Indian Pediatrics* seems to suggest. This kind of approach converts vaccines which are supposed to be a public health intervention available to all, into a luxury item used by a few. The use of such vaccines diverts attention from the problem of safe drinking water. The wealthy and the powerful shall therefore protect themselves by means of costly vaccines while the promise of safe drinking water shall remain a dream for the poor and the powerless who will continue to suffer from typhoid, cholera, hepatitis A, and a host of other such diseases.

Previous experience suggests that such segmentation in marketing as suggested by the IAP (Indian Academy of Pediatrics) recommendations where only the well-to-do will be targets for promotion or prescription of vaccines, does not hold good in India. Whether in the case of babyfood or drugs, the poor become victims of inappropriate prescription and use of drugs for which they have to pay dearly. Vaccines are now the main kind of drugs being dispensed by all doctors (especially pediatricians) and the costlier the vaccine, often, the more is the incentive for the prescribing doctor to prescribe them.

4. The question of efficacy of some of these vaccines

If vaccines are promoted as an alternative to other public health interventions, e.g., provision of safe drinking water, then the issue of vaccine efficacy needs to be addressed. Let us consider the example of vaccines against typhoid –either the Typhoid Vi polysaccharide vaccine or the oral vaccine; their efficacy is below 80%. These 2 vaccines do not protect against paratyphi A or B. Besides the effects of these vaccines can be overwhelmed by a larger dose of the infecting bacteria- a situation which can easily happen. Their effectiveness in children below 2 years of age is even less satisfactory. Also the period of protection conferred by the vaccine is not exactly known but is in the

region of only 2 years. In contrast safe drinking water can offer protection from a wide spectrum of diseases.

5. The prices of vaccines, and an analysis of the reasons that lie behind them

A Look at Some Vaccines and Sera, New And Old and their Prices

(*Source Of Data: CIMS, March-April 2004*)

Vaccines

Disease	Manufacturer and brand	Price per dose	Schedule of immuni-sation	Cost of schedule
Varicella	Aventis, Pasteur, Okavax	Rs. 1345	1 dose	Rs. 1345
Hepatitis A	Glaxo Smith Kline (GSK), Havrix	Rs. 712	2 doses followed by a booster at 6-12 months	Rs. 1424, and > Rs. 2100 if one adds a booster dose
Hepatitis B	GSK, Engerix-B	Rs. 323.50	3 doses at 0,1,6 months.	Rs. 970.5
Hemophilus influenzae B	Aventis Pasteur, Hibest	Rs. 526.00	3 doses followed by a booster for an infant	Rs. 2104 for an infant.
Rabies	Cadila HC, Verorab	Rs. 304.00	5 dose schedule	Rs. 1520
Combined vaccine against diphtheria, tetanus, pertussis, Hemophilus influenzae B.	Aventis Pasteur, Tetra Hibest	Rs. 4505 for a course	4 doses	Rs. 4505
Typhoid	Aventis Pasteur, Typhoral	Rs. 290 for 3 caps.	3 doses complete schedule , but protection lasts only 2 years.	Rs. 290

Sera

Disease	Indication	Manufacturer	Price per dose	Price per regime
Rh isoimmunisation	After childbirth in Rh –ve mothers	Bharat Serum	Rs. 2598.75	Rs. 2598.75
Antisnake venin	Only after venomous snake bite with evidence of envenomation.	Bharat Serum	Rs. 400	Rs. 2000 - Rs. 4000 for a mild to moderate envenomation

	Brand /Company A and its price	Brand /Company B and its price	Price variation: highest/ lowest x 100
Hepatitis B vaccine	Shanvac/Shanta Biotech Rs. 222. 00 for 1 ml.	Engerix-B/Glaxo Smith Kline Rs. 323.50	145 %
Anti D rhesus immunisation	Rhesonativ/P & U ltd. Rs. 464 for 300 microgram vial.	Matergam/Zydus-Biogen Rs. 2295 for 300 microgram vial	494%
Anti-Tetanus serum (human)	When patient develops tetanus	Bharat serum Rs. 564.20 for 500 units.	Rs. 564.20-Rs. 3385.20 for a dose of 500 units-3000 units

The cost of many vaccines is clearly more than what many Indians would earn in a month, and the cost of sera more than what many would earn in a year.

This brings us to the following points:

Are vaccines of necessity costly because of the high costs of production?

Only partly. Production of vaccines is a technically demanding exercise, with high input costs like those involving recombinant DNA technology, costs of maintaining horses, and of extracting antibodies from human serum.

Although the costs are substantial the prices listed above are unaffordable for those who have to pay.

6. Variation in Prices of Vaccines of Different Manufacturers

The prices of competitive brands and of multidose units indicate that retail prices are excessive.

a) The evidence we present is comparison between prices of different brands (see table below). The evidence from comparing costs per dose in single dose versus multidose vials is presented below.

Cost Comparisons of Single and Multiple Dose Vaccines

Name of Vaccine	Single dose vial and its price	Multidose vial (10 ml) and its price	Price reduction in cost of single dose
Hepatitis B vaccine Shanvac/Shanta Biotech	Rs. 222. 00 for 1 ml.	Rs. 1925.00 for 10 ml.	13.5%

Engerix-B/Glaxo Smith Kline Rs. 323.50	Rs. 323.50	Rs. 1683.00 for a 10 dose vial 47.9%

Source of data: CIMS, April 2004

The difference in single and multi-dose vials acts as a substantial incentive for the provider to vaccinate a person. In fact the massive Hepatitis B vaccination campaign have this reason behind them where the provider gets a multidose vial at subsidised and makes a healthy packet at the end of the campaign day courtesy the large number of people who have been vaccinated.

b) The tender rates for sera are also illustrative.

Evidence from Tender Rates

Retail price for Anti-snake venin	***Tender rate for supply of anti-snake venin as per L1 rates of TNMSC (valid for 01.11.2003 to 31.03.2005)***
Rs. 375.00-Rs. 400.00 per vial of 10 ml	Rs. 184.50

7. A question of rights

The question in this increasing targeting of vaccines to the few who can afford to the neglect of the majority who can benefit from basic public health interventions is of human rights: the right to basic entitlements like safe drinking water and sanitation rather than technical fixes that do not even raise the question of these entitlements. It is the question of access only to those who can pay for it, versus people's rights to be protected against important public health problems. It is the question of right to be protected by the drug regulatory authorities of the country from aggressive, irrational promotion of vaccines with only a commercial interest.

Other Issues Requiring Urgent Need for Attention and Regulation

1. The indigenous capacity for production of vaccines, especially in the area of new technologies is still rather weak

A beginning has been made with an Indian company making the Hepatitis B vaccine using recombinant DNA technology, which resulted in significant reduction in the price of the vaccine, but still there is a long way to go. Is it beyond the capacity of the Indian public and private sector to enhance its capacity in this regard? Given our large scientific base in biotechnology, it should not be difficult to do so. In contrast to the pharmaceutical sector where we have achieved self-sufficiency in the areas of bulk drug production and formulations, in the area of vaccines, especially incorporating those newer technologies the dependence on foreign imports is disturbing.

The corollary is that foreign manufacturers control a large part of the market and can exercise significant leverage on prices.

Sources, acting on condition of anonymity indicated that there is a significant pressure being exerted by the transnational companies on the government to undermine the functioning of the some of the leading domestic manufacturers of vaccines in the public sector like the Central Research Institute Kasauli. It would be interesting to investigate why the government has not far decided to upgrade these institutes.

2. The emphasis needs to be on production of vaccines and sera at lower cost which are relevant to India's health needs

The price of vaccines like those against rabies, and sera like those against snake venom, tetanus, rabies are prohibitively high. It has been the personal experience of this author of seeing rural patients mortgage their land to cover the costs of an anti-snake bite venom treatment. Rabies, tetanus, and snake-bites are diseases predominantly of rural and poor people, and their prevention deserves more attention than is available.

The prevention of rabies: who can afford it?

The prevention of a **severe** suspected rabid dog bite involves two drugs:
Administration of one of the newer vaccines like Rabipur, Verorab, (the older Semple type vaccine have fallen into disfavor because of reactions involving the nervous system) on 5 occasions:
Day 0, day 3, day 7, day 14, day 28, and day 90.
Each dose costs ~ Rs. 300.
Total for the schedule: Rs. 1500
In severe bites for more complete protection the administration of rabies immunoglobulin (RIG) is also recommended: This may be horse derived (Equine RIG) or of human origin.
The dose: equine rabies immunoglobulin: 40 U/kg.
Human rabies immunoglobulin: 20 U/kg.

The cost of rabies immunoglobulin

i. Equine: ERIG (Cadila-Newgen): 1000 u/5 ml. costs Rs. 625. (CIMS March-April 2004). For a 50 kg person with a dose requirement of 2000 i.u. The cost would be Rs. 1350.

ii. Human: Berirab (Aventis): Rabies Ig 300 i.u: Rs. 2225, 750 i.u. Rs.5565 (CIMS March-April 2004).

For a 50 kg the dose requirement would be 1000 i.u. And therefore Rs. 7790.

Total cost of prevention:
Vaccine + rabies immunoglobulin (equine): Rs. 1500+Rs. 1350= Rs. 2850.
Vaccine + rabies immunoglobulin (human): Rs. 1500 +Rs. 7790=Rs. 9290

3. The situation warrants reclamping of price control on vaccines

Earlier the scope of price control included vaccines. In fact the first objective of the Drug Policy 1986 read:

" Ensuring abundant availability, at reasonable prices, of essential and life saving and prophylactic medicines of good quality."

Even the modifications in drug policy 1986, in 1994, reiterated the same objectives as stated above. It did not cover vaccines in its price control order though.

However in the Pharmaceutical Policy 2002 we suddenly find mention of prophylactic medicines like vaccines having been dropped from the first objective of the policy:

"Ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption."

This omission is inexplicable.
Aren't vaccines life saving? Aren't they essential? Aren't they available at present at prices that cannot be considered reasonable by Indian standards?

Then why are they not under price control?

The present situation in many vaccines reminds us of the era, e.g., in the 1960s, in which our pharmaceutical industry was not developed, transnational corporations ruled the roost and drug prices in India were among the highest in the world.

Prices are high, unaffordable for the common man, and there are abnormal price variations documented as in the case above. Also the market for vaccines is not even a free market of the kind that the government places its faith in. In the production of sera and vaccines there are few players, with the foreign manufactures like Aventis Pasteur, GlaxoSmithKline playing dominant roles, and the market is characterized by oligopolies and virtual monopolies. Till a few years ago the only vaccine in the Indian market was Engerix-B, manufactured by GlaxoSmithKline. Formation of cartels which shall determine prices is a real danger and has probably already occurred This appears so because although in the section above variations in the prices of vaccines was shown particularly between Indian and foreign manufacturers, the prices in many vaccines is uniform and high. .

4. The marketing of vaccines has been unethical and bordering on the illegal

Direct to consumer advertising in the matter of drugs is not permissible as per Indian law. Vaccines are drugs given for prevention of diseases, and are governed by the same laws for their promotion. Yet they are being promoted with mass campaigns, pamphlets, letters circulated in schools, etc. With the intent of improving vaccination coverage under the universal immunization program, the government does run high profile advertising and information programs. However these do not serve any commercial interest, as the vaccines are provided free. Lately we have seen high profile advertising in the popular media (print mainly) on the vaccines, which are presently outside the government's universal immunization program. These have been misrepresenting facts and not providing either prescribers or consumers with unbiased and accurate information:

- A combined vaccine which provides coverage for DPT and Hemophilus vaccine at the cost of a few thousand rupees was heavily advertised in the newspapers (*an event which drew protests from the Indian Academy of Pediatrics. See box later below.)*
- For instance, letters were circulated in schools about the risk posed by jaundice to the student, and parents were advised that in view of the fact that their child eats and drinks out often that they should get their child vaccinated against Hepatitis

B. What the parents do not know, and are not told is that the commonest cause of food borne jaundice is hepatitis A, and not hepatitis B, which is in fact ***not*** **transmitted by food and water, and is only transmitted by unsafe injection, unsafe blood and unsafe sex.**

- Pure commercial interest of pharmaceutical companies and the private practitioners have driven the massive vaccination campaigns for hepatitis B. The companies provide multidose vials to private practitioners and nursing homes at vastly reduced prices, and the practitioners have been making a very healthy profit out of vaccinating healthy individuals.

- The top selling vaccine for prevention of rabies in India is heavily advertised through the medium of advertisements put out in the "public interest". Even local trains in Bombay carry them. Educating the public about rabies and the need for vaccination is a laudable objective.

  What this company does not do which is in the public interest is educate the doctors about the intradermal immunization technique which uses far lesser amounts of vaccines, on lesser number of occasions, and which has been approved and recommended by the WHO for prevention of rabies. This can reduce the cost of the treatment for the patient by 60-80%. The package insert of the vaccine does not mention this regime at all, while WHO documents and most textbooks of medicine now mention it.

  Obviously the company does not deem it fit to mention an equally effective regime that uses lesser amounts of vaccine in the interests of its "shareholding public".

Responses to the Unethical and Misleading Promotion of Vaccines

There has been no official response to the widespread unethical promotion of vaccines in India, except in response to a representation by the Indian Academy of Pediatrics.

Protest by Indian Academy of Pediatrics (IAP)

"Some of the multinational companies have been using the lay media (television, electronic media and newspapers/magazines) for placing advertisements pertaining to optional/combination vaccines. We opine that this is unethical. The IAP placed a formal complaint before the Drug Controller General of India and the Union Health Ministry. This led to the issuance of a letter by the Drug Controller to the concerned companies requesting them for the withdrawal of these advertisements."

Indian Pediatrics 2004; 41:239-244

Warnings by US FDA

It is interesting to note that in the year 2004 itself the manufacturers of Hepatitis A, Hepatitis B, Typhoid oral and Typhoid Vi vaccine who are incidentally are the same as in India were warned by the US FDA's Advertising, Promotion and Labelling Branch about violations of FDA sections because of misleading information in their promotional literature.
The US FDA sent warning letters in the year 2004 to manufacturers of vaccines for violations of norms for advertising, promotion, and labeling.

Hepatitis A and B Vaccines: Warning to GSK

This warning dated July 6, 2004 was related to Engerix-B® [Hepatitis B Vaccine (Recombinant)], Havrix® [Hepatitis A Vaccine, Inactivated], Twinrix® [Hepatitis A Inactivated and Hepatitis B (Recombinant) Vaccine] and read inter alia[1]:

The summary contains false or misleading statements regarding the live attenuated influenza vaccine and fails to reveal material facts regarding specific risks associated with the use of Engerix-B, Havrix, and Twinrix… We request that GSK immediately cease the dissemination of violative promotional materials for Engerix-B, Havrix, and Twinrix such as those described above….. Because the violations described above are serious, we request, further, that your submission include a plan of action to disseminate truthful, non-misleading, and complete information to the audience(s) that received the violative promotional materials.

Typhim Vi Vaccine: Warning to Aventis Pasteur

In their letter dated April 2, 2004 to Aventis Pasteur Inc, the FDA issued a warning for false or misleading effectiveness claims about the Typhim Vi vaccine. The warning inter alia read[2]:

…These materials (flashcards) mislead both consumers and professionals to believe that Typhim Vi is safer or more effective than has been demonstrated by substantial evidence or substantial clinical experience...

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[1] See http://www.fda.gov/foi/warning_letters/g4810d.htm

[2] See http://www.fda.gov/cber/adpromo/typhave040204.htm

…The reverse side of the referenced flashcard contains the statement, "Provides typhoid protection that requires just 1 shot." The placement of this statement without the mention of the need for a booster in close proximity leads the reader to believe that the shot gives complete protection with just one dose.

This statement, as it is presently written, is false or misleading because it implies that Typhim Vi is effective in protecting against typhoid without the need for reimmunization…Your approved PI specifically states, "An optimal reimmunization schedule has not been established. Reimmunization every two years … is recommended at this time." Your PI further states, "Based on the available efficacy data, vaccination with Typhim Vi may not be expected to protect 100% of susceptible individuals."

We would recommend this statement be revised to state, "Provides typhoid protection ***for 2 years*** [emphasis added in the original] that requires just 1 shot."

Rabies Vaccines: Warning for Omission of Important Risk Information

In their letter dated February 24, 2004 to Aventis Pasteur Inc on their promotional material for rabies vaccine and immunoglobulin, Imogam Rabies-HT [Rabies Immune Globulin (Human) USP, Heat Treated] and Imovax Rabies [Rabies Vaccine] the FDA warning inter alia read[1]:

The poster contains no risk information for either product. …The poster thus minimizes the risks of Imogam and Imovax and misleadingly suggests that these drugs are safer than has been demonstrated by substantial evidence or substantial clinical experience.

…The poster states.," Your single source for rabies protection." This implies that no other manufacturers supply products that protect against rabies.

All these letters specifically direct the companies to cease dissemination of promotional material.

The promotion of these vaccines has been in even more flagrant violation of the norms in India. However no such monitoring of promotional material occurs in India, despite misleading advertisements , promotional material which clearly misinform, and promotional methods which reflect increasingly, a view of vaccines as being little more than consumer goods.

Conclusion

Lately there has been aggressive promotion of newer vaccines, which are not part of the national immunization program. Some of these like the chickenpox vaccine do not address a felt public health need in India, and the appropriateness of the use of some others like Hepatitis A is not supported by data. The use of vaccines for individual water borne diseases as a substitute for public health measures like provision of safe drinking water constitutes irrational practice, and marker of a disturbing trend.

The costs of these new vaccines are exorbitant. Vaccines and sera for public health problems like tetanus, rabies, and snakebite are outside the reach of the common man. This situation can be remedied by encouraging domestic production of these vaccines (based on newer recombinant DNA technology) and sera (there is a high import dependence at present), and implementing price control on vaccines. The mechanism of price control is clearly warranted given the situation in the area of vaccines and sera with

[1] See http://www.fda.gov/cber/adpromo/rabave022304.htm

its high prices unaffordable to the common man, abnormal price variations, and only a few companies, (predominantly transnational) cornering a large share of the market which is at present monopolistic or oligopolistic in nature.

EPILOGUE: A CALL FOR ACTION

To the policy maker and administrator

- The people of India are already facing an unbearable burden of infectious and non-communicable diseases that take a heavy toll of health and lives. The government with its low spending on health increases this burden by depriving the people of the means to cope with these.
- The number of people, who do not seek care for their illnesses, is rising with the rise in healthcare costs.
- Drugs cannot be compared to ordinary consumer goods and the market for medicines cannot be allowed to become a 'free' market. Please see for yourself how this 'free market' behaves by inflating drug prices, sometimes to outrageous limits, for the consumer.
- Health is a fundamental right and access to affordable essential medicines is a prerequisite to realising that right. In the absence of the government's ability to provide people with essential medicines free of cost, it is the government's moral obligation to protect the patients from irrational drug prices that are driving people into debt and misery. The very least that the government can do is to ensure that the burden on the patients is the least that is compatible with the profitability of the pharmaceutical sector. The government has to, as it did in the past, balance the commercial interests of the pharmaceutical sector with the interests of public health in India.
- Please increase spending on health and strengthen the public health system as promised in the National Health Policy 2001. Access to affordable essential medicines has been the main objective of India's drug policy, but the pronounced pro-industry tilt in the policies of 1994 and 2002 has turned it into almost empty rhetoric. The primacy of this first principle of the drug policy has now to be restored.
- The drug regulatory system in India suffers from laxity, inefficiency and corruption. This is untenable in a sector that is so vital to people's lives. The policies from 1979 onwards have all called for strengthening of the drug regulatory apparatus and the creation of a National Drug Authority.
- The present fragmentation of drug regulated issues between the Ministry of Health, the Ministry of Chemicals and Fertilisers and the Ministry of Science and Technology leads to a lot of avoidable confusion and inefficiency.

To drug regulatory authorities

- There is good evidence from the data presented in this document that the poor patients of India are being taken on a ride by India's pharmaceutical market, which is nominally regulated but is actually 'free' in the negative sense of the term. The National Pharmaceutical Pricing Authority (NPPA) was formed with the express objective of protecting the consumer from violations of the drug price control order (DPCO) and from abnormal behaviour in the prices of those drugs that are outside price control. We plead with the NPPA to implement the DPCO with greater firmness and to respond to the highly abnormal variations in prices of decontrolled drugs while urging the government to add these to the price control regime.

- The Drug Controller General of India (DCGI) and the state drug control administrations are responsible for ensuring the quality of drugs, approving new drugs and preventing spurious drugs from reaching the consumer. We call upon these authorities to also stem the flood of irrational combinations and unsafe drugs in the market that lack efficacy and / or safety and certainly lead to wasteful expenditure. Should India have the dubious distinction of being the first and the only country to have allowed animal blood to be used as an anaemia preparation or being the last country to not ban unsafe drugs e.g. Analgin.

To consumer groups

- The price that consumers pay for their medications, the content of the medications themselves and their scientific rationale, the quality of the medications, the promotional practices of the drug companies, and finally the prescribing practices of doctors have received far less scrutiny from consumer groups than they should have. This has allowed the government to adopt policies which are clearly skewed in favour of the pharmaceutical industry and which encourage them to indulge in unfair trade and promotional practices.
- Drugs in India are often overpriced (by a factor of 20 to even 30 times in some cases), sometimes irrational and, not infrequently, of questionable quality. Prescriptions of doctors often violate scientific guidelines and contain drugs of dubious therapeutic (and enormous commercial) value that add nothing to their effect and everything to their cost.
- Consumer groups should lobby for heightened regulation and scrutiny of drug prices, drug contents, and quality by exerting pressure on the NPPA and the Drug Controller General of India. There should be a curb on unfair trade practices, including the unethical promotion of drugs and vaccines to doctors and the public. One should push for the use of essential drugs in generic form and for adherence to appropriately framed standard treatment guidelines while prescribing.

To academia and the public health professional

- The concept of essential drugs and the use of evidence-based standard treatment guidelines should form the core of the pharmacology-teaching curriculum in our colleges.
- In a country, where the majority of people are poor, the cost-effectiveness of drugs is an overriding factor in the framing of our prescriptions. The Essential Drugs List can be a guide to the most cost-effective, safe and efficacious drugs. Prescribing the latest congeners of existing drugs at three times the cost, merely on a hunch about their increased efficacy, to a patient, who cannot afford them is not only irrational but also unethical.
- Academia should take the lead in pointing out the irrational preparations for pain, infections, anaemia, undernutrition, diabetes and hypertension to the drug regulatory authorities.

To the practising doctor

- Your pen is very mighty. The bottomline of drug companies and the size of the hole in the patient's pocket depend on the way you wield it. If we critically evaluate the drug industry's claims on a new drug and hold back on prescribing it until the frothy hype of promotion has settled and the drug has made its way into standard textbooks, we stand to provide better, safer and more cost-effective care to our patients.

Document 1

PRICE MECHANISM IN OTHER COUNTRIES[1]

The basic concerns of the governments all over the world in respect of drugs and pharmaceuticals has been to ensure abundant availability at reasonable prices of quality products. The systems of regulation of drug prices in many countries has been adopted to control their health care spending. These systems have attracted attention as possible models for the regulations of drug prices in India also. Therefore the committee in its deliberations decided to visit some of the countries to study the prevailing systems in other countries. The Committee, in two separate groups, visited USA, Mexico, Canada, France and Egypt. In addition, the relevant material/studies were also collected for other countries. A synopsis of the systems prevailing in different countries is given below:

CANADA

Pricing

Canada has a unique system of controlling the prices of patented medicines that are sold in Canada. Towards this end, Canada has set up the Patented Medicines Prices Review Board (PMPRB). The mandate of the PMPRB is:

(a) To ensure that the prices of patented medicines charged by patentees are not excessive. All patented medicines sold in Canada are covered by the PMPRBs price fixation jurisdiction.
(b) To report annually to the parliament on its activities and on the pricing trends in the pharmaceutical industry, and;
(c) To report annually on research and development expenditure by the patented pharmaceutical industry and on the ratios of R&D expenditures to sales for individual patentees.

Prices of only those patented products are fixed which are charged by the patentee usually to a wholesaler or directly to a hospital or a pharmacy.

The PMPRB differentiates between "New" and "Existing" drug products. A new drug product is one for which the introductory price is fixed. Drug products are considered new in the year during which they are introduced in Canada. Existing products are those for which a benchmark price has already been fixed by the PMPRB. New drug products are categorized into three broad categories, namely, a breakthrough drug product, a substantial improvement drug product, and a moderate improvement drug product.

For the existing drugs the PMPRB while fixing the price follows either the Reasonable Relationship Test (RRT) or the Therapeutic Class Comparison (TCCT). Under the RRT,

[1] Reproduced from Chapter III of the Report *of the Drug Price Control Review Committee*, Dept of Chemicals and Petrochemicals, New Delhi, October 1999. Hereafter referred to as *DPCRC Report*, 1999.

it considers the association between strength and the price of the same medicine in the same or comparable dosage form. In the TCCT, it compares the price of the drug under review with the prices of the drugs that are clinically equivalent and are sold in same market at prices approved by the Board. For the new drugs, the PMPRB follows the International Price Comparison (IPCT). Under this, the price of the drug product under review is compared with the simple average of the ex-factory prices of the same strength and dosage form for each country listed in the PMPRBs regulations, which are; Germany, France, Italy, Sweden, Switzerland, United Kingdom and United States of America. When a direct comparison of the drug product and the review is not possible for a given country, the most similar strengths of comparable dosage form are considered. The median of the prices prevalent in these countries which would generally be the simple average of the middle two prices is normally adopted by the PMPRB as the price for the said product. Once fixed, the price continues as long as the product remains under patent and is allowed to be adjusted with the changes in the consumer price index. Thus in Canada, apart from fixing the prices, the Board also monitors prices of new products to determine whether they are reasonable. If products prices are found to be excessive, the companies may be asked to lower the prices, pay fines or return excess revenues collected.

Health Care System

Canada has a publicly financed, privately delivered health care system known to Canadians as Medicare. The management and delivery of services is the responsibility of the provinces and territories. The federal government's responsibility is limited to providing services to specific groups such as veterans, setting national standards, and assisting provincial health care services through fiscal transfers. The system is financed through taxes and employee/employer insurance premiums. The provinces must provide comprehensive coverage to everyone. Health services are delivered by the private sector; most physicians are private practitioners and over 95 percent of hospitals are operated as private nonprofit entities.

Reimbursement

All health care services provided by physicians, most medical laboratory tests, and all that is provided in hospitals procedures are covered for reimbursements. The reimbursement of non-hospital-prescribed drugs is based on the different provincial plans with eight provinces providing universal coverage with varying levels of co-payments and two provinces cover only the elderly and welfare cases.

Other Cost Control Measures

The main mechanism is the control of patented drug prices, as described above. Some provinces, such as Ontario and British Columbia, have instituted other measures, such as generic substitution, price freezes, and reference pricing.

FRANCE

Pricing

Once a product is granted market authorization and approval as a reimbursable product by the Transparency Commission, it is referred to the Medicines Economic Committee (CE M). The Committee sets a reimbursable price after negotiations with the manufacturers. For fixing the consumer price, the Committee does not carry out a cost study as is done in India. However, the prices are worked out using several criteria, including internal comparisons with existing products; therapeutic merit; and contribution to the domestic economy. In additon, for the drugs that account for a significant fraction of expenditures, an "Envelop Globale" applies, a comprehensive revenue limit which means that if the revenue is higher than targeted, the price is cut to bring down the government total spending on the drug within the target.

For the reimbursable drugs, margins for the wholesalers and the pharmacists are controlled. The price before tax, of reimbursable medicines, is the sum total of the manufacturers price before tax negotiated between the company and the CEM, the wholesaler margin (which is 10.74% of the manufacturers price before tax) and the Pharmacists margin (which varies from 8.26\8% to 44.83% of the manufacturers price before tax). Added to this is VAT of 2.1% for reimbursed drugs and 5.5 percent for non-reimbursed drugs is also considered.

The Government of France has adopted a cost cutting measure by adopting a deliberate policy of encouraging generic prescriptions. Doctors are expected to prescribe at least 15% generic drugs. The prices of generic drugs are kept 25% to 30% below the original product prices. 91% of the sale of medicines through retail Pharmacists in France is on the reimbursable list.

The system of controlling consumer prices through the reimbursable list and provision of encouraging generic prescriptions have reported not retarded the growth of the pharmaceutical industry. In fact, both have worked in a cohesive way to provide modern medicines at affordable prices.

Health Care System

The French health care system covers the entire population. It is funded by employee/employer contributions (74% and patient co-payments 26%) Patient co-payments are paid either by private insurance companies or by nonprofit insurance plans.

Reimbursement

Using a number of criteria, the Transparency Commission decides whether the drug is eligible for reimbursement. Once it is accepted, the 'Economic Committee on Medicines decides the actual reimbursement price. Companies have to provide detailed data on

costs, sales, and investments. The reimbursable products are distributed into three categories:

(a) Hundred percent reimbursement granted for certain products like life saving drugs and very expensive medicines.
(b) Sixtyu five percent reimbursements granted for products intended for disorders and diseases that are not very serious.
(c) Thirty five percent for most of the other products

More than 90 percent of the sale of medicines through retail pharmacists are, thus, included in the reimbursement list.

Other Cost Control Measures

The patient has to pay the amount that is not reimbursed, although many segments of the population are exempt from this co-payment requirement. Primary care physicians are given prescribing guidelines and asked to limit the growth in total reimbursement. There is a tax on promotional spending by pharmaceutical companies. The tax varies between 9% and 20%, depending on the proportion of sales revenue spent on promotion (the higher the proportion, the higher the tax). The government enters into contractual agreements with the pharmaceutical industry to make sure that the government health insurance funds do not exceed an annual ceiling on health expenditure, including spending on pharmaceuticals. If the budgets are exceeded, pharmaceutical companies are asked to make a collective contribution toward the health care budget deficit (1996). Such payments take the form of taxes on advertising, taxes on sales, and taxes on extraordinary sales increases.

EGYPT

Health Care System

Egypt has created an unified Drug Control Authority (DCA) that regulates the industry in technical, quality control, production, distribution as well as pricing matters. In Egypt, the distribution of locally manufactured and imported drugs is undertaken both in the public sector and through the private distribution channels.

The Government distribution network which is being operated through the Egyptian Pharmaceutical Trading Company is very well organized and reaches down to the community level even in remote areas. The Government supply chain is also used for subsidizing certain medicines as per the Government policy. There are more than 20,000 retail/pharmacy shops distributing the medicines to the consumers. All shops are licensed and have to have pharmacist to dispense medicines.

Pharmaceutical Pricing

All medicines sold are subject to price control at manufacturer and consumer levels. The manufacturer prices are fixed after doing cost studies of the medicine, the details of which are submitted to the Government by the manufacturers. On the cost of raw material and packing material a margin of 30% is allowed towards administrative costs which are basically the manufacturing cost. A profit of 20% is allowed to the manufacturer for the locally manufactured products. On the imported drugs a margin of 12% as profit is allowed. 11% is allowed on marketing cost on the ex-factory price.

While fixing the consumer price, it is ensured that similar drugs are similarly8 priced. The profit of the wholesalers are regulated at 7%. The retailers are allowed a profit margin of 20% in the consumer price fixed by the Government. To ensure that imported items are not overpriced, there is a departmental Committee that determines the reasonableness. In Egypt, there are presently around 4000 approved medicines. It is their policy not to allow unnecessary formulations packs and dosage forms to be produced or sold.

Other Measures

It is a Government policy to restrict the number of manufacturers of medicines. Only 4 to 5 units are allowed to manufacture a drug for which the government fixes the prices. In case a sixth company wants to manufacture and sell the same drug, it will be permitted only in case it accepts to sell the product at least on an average 30% below the price of others.

MEXICO

Health Care System

Every drug and pharmaceutical that is marketed in Mexico has to have a marketing approval and the concerned company is required to register its products with the Ministry of Health. The manufacturers\ also needs to comply with other regulations related to price, patents, etc. stipulated by the various departments of the government. In order to register a product in Mexico, a drug has to comply with safety, efficacy, purity, stability and quality standards laid down by the national and international agencies, as provided in the law.

In Mexico, about 70% of the total population is covered through various social security schemes. While the security and Social Services Institutes for Estate Workers (ISSTE) provides health cover to the employees of the government, the Mexican Institute of Social Insurance (IMSS) provides the required cover to the workers and their families. Further, mobile doctors periodically visit the villages having population of 500 or less to dispense the required medicines free of charge. A proper system of registration of herbal preparations is also in position. In rural areas, adequate freedom is given to the practitioners of indigenous systems. Use of Homeopathy is also regulated and some prestigious institutions are engaged in imparting education and training in the respective areas.

In view of the freedom given to the companies with regard to the pricing of their products, greater thrust is being laid on expanding the coverage by various social security and insurance scheme. Gradually the health care enforcement is shifting into the hands of the insurance companies. However, at the same time the Mexican government has taken steps to reinforce the social security system and to increase the coverage under various scheme of the system.

Pricing

All the Pharmaceutical products are subject to price fixation by the government. A highly flexible system of pricing is being followed, mainly baed on the details given by the individual companies. This system takes into account factors like investment, production performance, sales level, inflation, exchange rate etc. The Ministry of Commerce and Industrial Development (SECOFI), which looks into the pricing aspect of pharmaceuticals, examines the details as furnished by the companies. However, no rigorous scrutiny of these details, and the price as claimed by the company in undertaken.

Prices of new products are fixed at the level requested by the Pharmaceutical company in certain situations like if there are no similar products or the generic is available in non-comparable pharmaceutical forms, products for which generics exists in the market but (can sustain a new therapeutic application) have a better side effect profile, or provide advantages in its application, in the case of products which have been reformulated with the corresponding authorization of the Ministry of Health, they are considered as new products.

Since the liberalization in 1990-91, prices of pharmaceuticals have reported risen between 50-100% in 1994. It was observed during the visit of the team in June 1999 that the pharmacies were selling medicines at widely publicized discount of 25 to 30% which indicates the liberal and arbitrary fixation of the prices of medicines in that country. A considerable difference in prices of branded and generic formulations manufactured by the same/different companies was also observed in Mexico. However, mostly single ingredient formulations are encouraged which, in turn, ensures rational use of drugs.

The manufacturer's selling price varies depending on whether the products are sold through the public or private sector. In the price fixed , the manufacturer retains a margin varying between 7 – 10%. The wholesalers margin is 18.5%. There are two different mark-ups for Pharmacists – One for pharmaceuticals launched before February 1975 and one for pharmaceuticals launched after that date.

Price Structure at Retail Level

	A	**B**
Manufacturer's selling price	100.0	100.0
Wholesaler's selling price	118.5	118.5
Pharmacist's selling price	140.2	140.2

A = products launched before February 15th, 1975
B = products launched after February 15th, 1975

Source: IMS Mexico Pharmaceutical Index.

ITALY

Health Care System

A comprehensive national health service covers the entire population. The system is funded mainly by general taxes and co-payments.

Pharmaceutical Pricing

Companies are free to set prices for prescription drugs that do not seek reimbursement: prices of reimbursed drugs are controlled. Reimbursed generics have to be priced 20 percent below the original. OTC prices are not controlled. For reimbursed products, the wholesaler margins is set at 10 percent of the manufacturer's price. For products approved through the centralised EU procedure, the wholesaler margins depend on the price of the products. Pharmacy margins for reimbursed products are set at 40% of the manufacturer's price. VAT is 10 percent.

Reimbursement

The reimbursement price of prescription drugs can be no higher than the "European average", which was historically calculated on the basis of the average price in France, Germany, Spain and the U.K. A new system of average prices baed on a 12-country comparison has recently been adopted. Drugs are placed in one of three classes that determine the level of reimbursement (0 percent, 50 percent, 100 percent), depending on their efficacy and need. Products are removed from the reimbursement list if their prices are raised above the European average level. Prices of products that are not reimbursed can be raise once a year.

Other cost Control Measures

Depending on the drug category, patients may have to pay 50 percent of the price. They also pay a flat co-payment for every prescription. Some groups are exempt from co-payment requirements. There is an annual global budget for pharmaceutical reimbursement. Primary physicians have some prescribing guidelines. Generic substitution (substituting one generic for another) is permitted under certain conditions.

GERMANY

Health Care System

The health care system is decentralized with – 700 self-governing non-profit insurance funds (called sick funds) financed by employee/employer contributions. Sick funds must accept everyone for coverage. A part of the population (about 8 percent) whose income exceeds a certain level is allowed to buy private insurance.

Pharmaceutical Pricing

Companies are free to price prescription drugs and generics, but reimbursement is controlled. Companies can change their prices freely. Wholesaler and pharmacy margins are fixed by law and depend on the ex-factory price of the drug. VAT is 16 percent.

Reimbursement

Once a drug is approved, it automatically qualifies for reimbursement, unless it has been specifically excluded. Prices for reimbursed drugs are controlled by reference pricing. Drugs are put into a reference class on the basis of therapeutic consideration; all drugs in a class are reimbursed at the same level. Patients pay the difference between the reference price and the market price. Since 1996, all on-patent drugs have been exempt from reference pricing. Reference prices are reviewed every year.

Other Cost Control Measures.

Patients have to pay a fee per prescription which is dependent upon pack size, although some groups are exempt from this requirement. In 1993, global budgets have been replaced by indicative budget for individual practices although global budgets were re-introduced in late 1998. Generic substitution is legal if permitted by the prescriber. Because of the historically high consumption of branded drugs compared with generics, the government has also made a conscious effort to encourage generic use. This allied with budget constraints on physicians has led to a market in which in 1998 more than 40% of prescription were for generics.

JAPAN

Health Care System

Universal medical coverage is part of the social security system. Most of the revenue for the system (approximately 90 percent) come from general taxes and employer/employee health insurance funds and the rest is paid directly by patients. The health care system is characterized by universal coverage, free choice of health care providers by patients and fee-for-service payment to service providers. Hospital and clinic physicians may sell drugs directly to patients.

Pharmaceutical Pricing

The manufacturer's prices are not directly controlled, but reimbursement prices are set, effectively acting as price controls. Companie have to sell to wholesalers who supply to

the national health system at a set discount; the wholesaler has a markup of approximately 4 percent.

Reimbursement

Almost all prescription drugs are on the reimbursement list. The reimbursement price of a new product is determined by comparing it with similar products on the list. The price allowed depends on the product's relative efficacy, safety or usefulness. If the drug is innovative, a premium of upto 30 percent is allowed; if it is "useful", a premium of upto 4.5 percent is allowed; if it is a generic, it h as to be priced at least 10 percent lower than the originator drug. If there is no similar drug on the market, the price of the product in other developed countries and the cost of manufacturing may be taken into account. Price are revised every two years (although annual revisions have been made recently). Price revisions are based on the "reasonable zone" (R-Zone) method; prices are revised by the amount by which the reimbursement price deviates from the actual discounted market price (the R-Zone is currently 5 percent). Price cuts maybe mandated if the sales of the drug exceed expected sales targets. Since doctors receive the reimbursement price, they can profit from whatever discount they get from wholesalers.

Other Cost Control Measures

The Government is considering additional measures such as cross-country comparisons and reference pricing.

UNITED KINGDOM

Health Care System

The National Health Service (NHS) provides universal health coverage. It is funded by general taxation (96 percent) and patient co-payments (4 percent). Patients have to register with general practitioners (GPs), who control access to specialist. GPs are organized in groups and paid by capitation. There is ma move toward primary care groups, which consist of 50 or so GPs providing mot health care services.

Pharmaceutical Pricing

The prices of branded prescription drugs are not controlled at launch. Generic prices are controlled – the price is set at the level of the weighted average price of the main suppliers. OTC pricing is not controlled. Prices may be lowered at will, but price increases are restricted to the products of companies whose profits fall more than 25 percent of allowed profits. For sales to the NHS, wholesalers get a mandated 12.5 percent discount from the manufacturers' price. Pharmacies get a flat dispensing fee per prescription and are reimbursed at the wholesalers' list price (hence it is in their interest to negotiate the lowest price from the wholesalers). VAT is 0 percent for NHS prescriptions but 17.5 percent for OTCs and private prescriptions.

Reimbursement

All drugs are reimbursed, unless they are on the negative list, which consists of products in eight therapeutic categories. Prices of drugs are not directly controlled through price increases are.

Other Cost Control Measures

The major form of market interventions is the pharmaceutical price regulation scheme (PPRS), which regulates company's profits on sales to the NHS. Maximum profits are negotiated on a company-by-company basis and are based on the rate of return on capital in the U.K., investments in the U.K., and level of long-term risks. Companies whose sales exceed their capital employed by a factor of 3.75 are granted a maximum return on sales. Companies that exceed their maximum return on capital or return on sales have to reduce their profits by repaying the excess in cash or lowering existing and future prices. GPs who belong to fund-holding or primary care groups have global budgets provide all services. Spending is tracked monthly by the prescription analysis and cost (PACT) system. Most patients are charged a flat fee per prescription, or they may pay a certain amount per year for an unlimited number of prescriptions. Generic substitution is illegal but the use of generic is on the rise. Promotional spending is limited to a percentage of ssales to the NHS.

SPAIN

Health Care System

The national health care service provides universal coverage. It is funded by general taxation (50 percent), social security contributions (22 percent), co-payments and other out-of-pocket expenses.

Pharmaceutical Pricing

Launch prices of prescription drugs are controlled. Prices are set using a host of factors, including cot of production, profit allowance and anticipated volume of sales. The profit allowance is set by company. A reference-price ystem is being worked on for multisource drugs with the same ingredient, strength and dosage forms. Generics are priced 25 percent - 30 percent below the originals. OTCs are not controlled. Wholesaler's margins are set at 12.4 percent and pharmacy margins are set at 43.5 percent of the manufacturer's retail price. VAT is 4 percent.

Reimbursement

Reimbursement is controlled and is based on a number of factors related to therapeutic value. Prices of all drugs on the reimbursement list are set. Reimbursement may be refused if other, cheaper drugs are already on the market. Reimbursement prices may be

changed if the change is justified by the manufacturer. In the past, the Government has mandated across-the-board price cuts and price freezes for all drugs on the reimbursement list.

Other Cost Control Measures

Companies can be asked to return a part of their reimbursement sales to the Government. For reimbursed drugs most patients pay 40 percent of the cost. Health care centers have global budgets covering all forms of treatment. Autonomous regions may have additional cost control policies. Doctors' prescribing behaviour is monitored and high prescribers may be warned. Pharmacists may substitute one generic for another. Promotional expenditure for a product is set at 12-14 percent of the manufacturer's selling price.

THE NETHERLANDS

Health Care System

There is a national system of health care, but different parts of the system are financed in different ways. Serious illnesses and disabilities are fully funded by the Government through general taxes and income-related payments. Acute care is funded by semipublic sick funds; people with incomes exceeding a certain amount can opt for private insurance.

Pharmaceutical Pricing

For prescription drugs and generics, the maximum manufacturer's price is the average of the prices in Belgium, France, Germany and the U.K., taking into account the impact of parallel imports into these markets. OTC prices are not controlled. Prices are revised biannually as the prices in the reference countries fixed. Pharmacies are paid a fixed dispensing fee per item. VAT is 6 percent for prescription drugs and 17.5 percent for OTCs.

Reimbursement

Listing for reimbursement is based on therapeutic and clinical grounds. Drugs that are classified as being unique therapies for hitherto untreatable diseases can be priced by the manufacturer, though few such drugs have been recently admitted to the reimbursement list. Reimbursement limits for other drugs on the reimbursement list are based on a reference pricing system based on the WHO defined Daily Dosage. The maximum reimbursement limit for a class of drugs is based on the price of the product priced just below the average price. Generic prices are taken into account in this calculation. Reimbursement status and limits are not reviewed in a periodic or systematic way.

Other Cost Control Measures

Most patients have to pay 20 percent of the cost of all outpatient care, including prescription drugs, upto a maximum level. There are indicative budgets prescribing guidelines for general practitioners. Generic substitution is permitted with the consent of the physician and the patient.

SWITZERLAND

Health Care System

The different cantons (sates) largely decide health policy, though insurance and the supply of drugs are federal responsibilities. Health care is financed by sick funds and private insurance firms (67 percent), general taxation (5 percent) and co-payment (28 percent). An increasing proportion of the population is insured by private insurance companies and managed care organizations.

Pharmaceutical Pricing

Manufacturers are free to set prices for prescription drugs except for those on the reimbursement list. Generic prices must be below 25 percent of the original if they are to be reimbursed. OTC prices are not controlled. Prices of non-reimbursed products can be changed freely. Wholesalers' margins rnage from 11.1 percent to 17 percent, depending on the price of the product. Pharmacy margins range from 70.6 percent to 26.1 percent. The margins of OTCs are not controlled. VAT is 2 percent.

Reimbursement

Admission to the reimbursement list is based on a number of factors related to efficacy, need and cost-effectiveness. Reimbursement prices are set by factoring in considerations such as prices in the country of origin, prices in other European countries (Denmark, Germany, The Netherlands) and innovativeness of the drug. Foreign imports are allowed an additional premium of 25 percent to compensate for transaction costs. Reimbursement status and prices are guaranteed for 15 years.

Other Cost Control Measures

Most patients have to pay out of pocket upto an annual deductible amount. After that, they have to pay 10 percent of all medical costs, including those for pharmaceuticals, upto a limit. Some cantons monitor physicians' prescribing patterns. Generic substitution is illegal.

UNITED STATES OF AMERICA

Pricing

The prices of pharmaceuticals in the United Sates are, by and large, regulated by market forces. The pharmaceutical companies are free to price their products, except that any

sales to the government (Medicaid) must be at a specified discount to the market price. Although "Price Control" is an anathema to the pharmaceutical industry in the US, there is, however, a growing concern among the opinion leaders and public regarding the high price of drugs. There has been an ongoing debate in the US Congress with regard to high cost of health care and the issue of high price of drugs has formed a very important part of such debates. A growing need is being felt to manage prices of pharmaceuticals at reasonable levels for the consumers. President Bill Clinton's Health Security Act has proposed an Advisory Council on Breakthrough New drugs to evaluate the reasonableness of the prices of new drugs. Reasonableness was to be evaluated based on several criteria, including cost and international comparisons, based on the lowest price of the group of more than twenty countries. If a price is deemed unreasonable, the drug could be denied reimbursement under public programmes. Thus, under such a system the manufacturers are required to strike a balance between high per unit profit with low turnover and a reasonable profit on high turnover.

A difference in the prices currently offered by manufacturers exists between institutional (hospital/long-term care facilities) and community pharmacies. These differentially priced drugs are to be sold to the patients and employees of these institutions only and are not allowed to be sold to the general public under an Act. A noteworthy feature is that despite the absence of price control, cases have been filed in courts against the discriminating prices offered by the drug manufacturers to such managed care companies, as these special prices were not offered to communities/pharmacies. But the pharmacies have agreements with the various insurance companies who reimburse the cost of each drug as per the agreed terms. Thus, there is no retail price fixed by the manufacturers and each pharmacy can sell a drug at its own price subject only to the agreement with the insurance companies. The price reimbursement for each drug also differs from one insurance company to another even for the same pharmacy. Further, some surveys conducted by the local body in New York brought out that the price of the same medicine different widely in the nearby pharmacies in the same locality. This is contrary to the basic principle of competition where prices are not allowed to vary significantly.

To the wholesaler, sale by the manufacturer is made on the basis of the average wholesale price plus a margin of around 2%. The pharmacy gets a margin of around 15% plus a fixed charge of around 1.5 USD. The manufacturers offer higher discounts for greater volume of sale to the pharmacies.

Health Care System

By and large, all the citizens of the United States of America are covered by Health Insurance Schemes. Such insurance coverage fall into two categories; namely, those provided by the private insurance companies, those provided by government programmes (Medicare, Medicaid). However, the health care system in the U.S. is managed mainly by private companies, in terms of both funding and service provision, though there are publicly funded programmes that provide health care to certain segments of the population. Care for the elderly is covered by Medicare, entitlement program that reimburses many medical benefits but currently does not include a comprehensive

outpatient benefit. Care for the poor is provided via Medicaid which includes comprehensive drug coverage. Additional publicly funded schemes cover defense personnel and war veterans (Veterans' Administration). The private health care system consists mainly of health maintenance organizations (HMOs) and other forms of managed care organizations, which are financed primarily through employer/employee by cash paying patients, this share is declining as third party payers expand, particularly in the government sector. Further Co-payments are almost universal with increasing use of tiered co-payments to steer demand towards generic or on-fornulary drugs (for which the managed care organization has usually negotiated a manufacturers discount).

Of late, there has been a shift towards managed care from merely payment for services. This managed care includes inculcating health habits and provision of facilities for rest and recreation, games, anti-smoking and anti-drinking clinics. In the USA, private insurance being a business activity, there is always a conflict between cutting costs to increase profit on the one hand and on the other, the need to provide efficient and satisfactory services to attract more customers. Most companies, especially those providing services at the lower end appear to place severe restrictions on the drug costs to reimburse, the number of dys of hospital care, and a variety of similar cost cutting strategies. Such measures are some times resisted by the beneficiaries and certain changes have been effected in the relevant Act. Therefore, the "managed health care" mechanism is still in the nascent stage and will take some more time to gain the confidence of the public.

People, who are not covered either by the private insurance or by the Government managed health schemes, have to pay from their pockets. The affordability of drugs for these people is a serious problem as there is neither a fixed price for any drug nor is there any system for determining a fair-price, with manufacturers supplying their products at different rates to different entities.

INDONESIA

Pricing

Although pharmaceutical prices are not directly controlled in Indonesia, however, the intended price of a product including cost calculations has to be submitted with the application for registration. Pharmaceutical companies are required to explain any large price differentials between the Indonesian price and the price in other countries. If the explanation is unsatisfactory, the Food and Drug Control Division (FDCD) can refuse registering the said product.

There are no official regulations on pharmaceutical mark-ups and discounts. However, the Food and Drug Control Division determines a maximum Pharmacists selling price for each product based on the manufacturers' selling price, which effectively limits the pharmacists' mark up. The maximum pharmacists' selling price has to be displayed on the packaging of each product and the list of maximum prices product wise have to be displayed in each

pharmacy. Retail prices for products on the essential drug list, are fixed by the Food and Drug Control Division.

At the distributor and the wholesaler level, profit margins vary according to the nature of the products, i.e. for imported and indigenously manufactured respectively. The indigenously manufactured products are sold with a list price known as "net price to the apotik". The distributor/wholesaler mark up is about 20 percent. For imported goods when the importer is also the distributor and wholesaler, the mark up on landed cost varies between 20 percent and 40 percent. However, when the importer does not perform wholesale and distribution functions, the mark ups at each level of distribution after the goods leave the importer follow practically the same pattern as local products.

Changes in prices have to be notified on the Food and Drug Control Division of the Government of Indonesia and the said division has the power to ask for justification from the companies in case the price increase is considered to be excessive.

VAT at 10 percent is imposed on the manufacturer's selling price and the distributor's selling price for all pharmaceutical products except those included in the essential drugs list.

COLOMBIA

Pharmaceutical Pricing

Colombia started to implement total control over drug prices in 1968. Since then, price regulation has gone through a number of phases and forms. Recently the scheme was changed to combine freedom for a wide range of products with price control for a limited number. Since 1992, essential drugs with fewer than five suppliers and so-called "critical drugs" (in total about 20 percent of the market) have been subject to "monitored freedom" under which the producers or imprters can change the maximum selling price to the public, but must inform the Ministryof Development in advance of a price change. The Ministry can require manufacturers to present cost analysis in support of price increases and can also override the producer and impose the price level if it deems appropriate.

One of the reasons the scheme was changed was that significant differences in prices for the same product occurred as manufacturers submitted different cost justifications. Furthermore, the manipulation of periodic price adjustments by the Ministry of Health introduced a political element and sometimes led to conflict between the producers and the authorities. Those products with prices that did not keep up with inflation often disappeared from the market, creating artificial scarcity.

In 1994, however, the Colombian Government dropped the experiment with "monitored freedom" and returned to a system whereby prices to the consumer for monitored drugs had to be less than 3.4 times the production cost of the drug. The principal reason for this

turnaround was lack of government capacity to follow up price changes under "monitored freedom".

CONCLUSION

A study of various country's pharmaceutical industry profile has shown that there is a system of pharmaceutical price management, whatever may be the name given to it. Even in the countries that are votaries of a free market economy, when it comes to medicines, there is a system of checks and balances existing in such countries. Medicines being an essential commodity combined with ignorance of the common man of the "benefit-risk profile" of a drug price management/control becomes not only essential but inevitable as a tool of public policy for consumer protection.

Marketing approval for every drug whether imported or indigenously manufactured and registering them with the appropriate government authority has been accepted as a fundamental requirement for every pharmaceutical product. Countries have adopted the system of reimbursement pricing, reference pricing, patented product pricing etc. in order to put a moratorium on the prices of pharmaceutical products that can be charged. In some countries, a cap has been put on the margins allowed to the wholesalers and pharmacists. A comparative position is displayed by a bar-chart enclosed herewith (exhibit 3.1). Further, the declining trend in price in different countries after initial launch over a period of time, is shown in a graph (exhibit 3.2). In others, registration of prices is insisted at the time of seeking marketing approval. Further, there are various systems of ensuring reasonable health cover either by the public funded programmes or through the private companies in the health and insurance sectors.

India is on the threshold of the product patent regime in the pharmaceutical sector. The price control system that is adopted today will have to necessarily take into account the challenges and conditions that will be created in India after the introduction of product patent. With the reduction in trade and tariff barriers, India has moved closer to other countries of the world. With the introduction of product patent, new and monopolistic products are bound to hit the Indian market from all over the world. Since the consumer patients in this country are not covered by any social security system, as is in existence in many of the developed countries, the need of making available the latest drugs, many of which would be patented with exclusive rights to the patentee, at affordable prices would become imperative. In this scenario the experience and system as adopted in various countries of the world could be considered with necessary modifications to suit our conditions. The following would, however, need to be ensured in this regard:

(i) Adequate availability of the required medicines at reasonable prices. There is steady growth of the generic drug (off patent) industry, which today caters to almost the entire Indian market and is owned by the Indian as well as multinational companies. In this background, pricing of (a) drugs with inadequate competition and (b) patented products would ensure

growth of Indian drug industry as well as catering to the medical needs of the consumers.

(ii) As a medium and long term strategy, adequate health insurance cover both by the public and private sector needs to be provided so that the dependence on price control measures could progressively reduced.

Document 2

PRICING AND PRICE CONTROL OF DRUGS AND PHARMACEUTICALS[2]

…. 6.10 While replying the specific query of the Committee about the drug price control systems in other countries, the Department of Chemicals and Petrochemicals submitted the following details in a written note: -

"Price control in one or other form is exercised in all the countries. In the developed countries it is exercised through reimbursement scheme and through Insurance Scheme. The feature of the various methods used are as follows: -

(a) Cost Plus

The Cost plus method bases permitted rise on the cost of production, allowance being made for marketing and R&D expenditure. The low ratio of direct cosst to total cost in the pharmaceutical industry makes the cost plus pricing method potentially a difficult technique to apply without any bias.

(b) Internal Comparison

In this system prices are fixed by reference to comparable drugs already on the national market, concessions being made to innovative products with therapeutic advantages. This means that similar products will be similarly priced leaving little room for price competition. In this system the prescribing freedom of the Doctors is not compromised. The prices of new drugs in which there is no equivalent on the national market may be determined by using the price in another country. Spain, Luxembourg and Portugal follow this system.

(c) External Comparison

In external comparison the price of a particular medicine in other countries is taken as the standard. In Ireland, for example, external comparison is used by linking local prices to a Five country formula.

In most of the member states of the European Community, pharmaceutical expenditure is also controlled by one means or the other. Two principal ways of curbing expenditure is by reimbursement control or cost containment. The methodologies used are as under: -

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[2] Extract from Chapter VI of *Report on Pricing and Availability of Drugs/Pharmaceuticals*, Ministry of Chemicals and Fertilisers (Dept of Chemcials and Petrochemicals), 15th Report of the Standing Committee on Petroleum and Chemicals (August 2001), Thirteenth Lok Sabha , Lok Sabha Secretariat, New Delhi.

(a) Positive List

A positive list contains those drugs for which reimbursement is being made partly or wholly by the Government. In countries with product-by-product price control, a positive list is a integral part of the price control.

(b) Negative List

A negative list is a list of those drugs which are not reimbursed at all. An inclusion of any drug under this list automatically results in non-prescription of this drug.

(c) Reference Prices

In this method the reimbursement limit for a group of identical or equivalent products is fixed. Reimbursement is made only on the basis of the reference price and any higher price has to be borne by the patient.

(d) Volume related price

Under this method, practiced in France, in order to tackle new mega priced drugs, a sales volume is fixed. Should actual sales exceed the forecast sales volume, the price will have to be reduced through negotiations between the authorities and the manufacturer.

(e) Promotional Expenditure Control

Through this method an attempt is made to keep the promotional expenditure under control either by imposing a tax on such expenditure or by restricting the amount that can be spent on promotion expenditure.

(f) Transfer to OTC status

This is an alternate to the negative list because one a drug is specified as an OTC drug, the consumer has to meet the entire cost.

(g) Economical prescribing habits

In some countries the authorities have tried to promote economical prescribing habit in order to encourage pricing of cheap, safe and effective drugs. This is achieved buy publishing an essential drug list or by prescribing disincentives for Doctors who are found to be exceeding the average price for drugs prescribed.

(h) Percentage of co-payment

In a number of EC countries, the patient is obliged to pay a percentage of the cost of the drugs prescribed. In some countries the percentage is linked to the financial and medical condition of the patient.

6.11 The Department has submitted a statement showing the drug price control systems in European countries as under: -

Country	Individual drug Price control	Basis
Belgium	Yes	Internal comparison (cost plus)
Denmark	No	Reimbursement control-reference price system
France	Yes	Internal comparison
Germany	No	Reimbursement control-reference price system
Greece	Yes	Cost-plus for locally produced, external comparison for new drugs.
Ireland	Yes	External comparison
Italy	Yes	Internal comparison (cost-plus)
Luxembourg	Yes	External comparison (Belgium)
Netherlands	Yes	Reimbursement control-reference price system
Portugal	Yes	External comparison
Spain	Yes	External comparison but control of profit Company-by-company
U.K.	No	Rate of return fixed company-by-company Through negotiations with the D/o Health, UK
Austria	Yes	External comparison, (cost-plus)
Finland	Yes	External comparison, (cost-plus)
Sweden	Yes	External comparison, (cost-plus) profit margins

6.12 While analyzing some prominent pricing system, the Department submitted the following details: -

"The Japanese drug pricing system has to be viewed in the background of the existing medical insurance system. The National Health Insurance Drug Price list is an itemized list of pharmaceutical products which can be used for insurance of medical care. Based on surveys the list is revised periodically. The list contains approximately 13,500 drugs and the Drug Price Calculation method is laid down by the Chuikyo (The Central Social Insurance Medical Council).

China follows the cost plus system for fixing prices of drugs. The State Administration or Prices analyses the cost of production of a particular drug as conveyed by the factory

which manufactures it and adds an acceptable level of profit margin to it to arrive at a fair price. This fair price is conveyed to the State Administration of Pharmaceuticals and to the sub-office of the State Administration of Pharmaceuticals, who specifically deal with the price of a drug. The official price of each drug is finalized after the approval has been obtained form the State Administration of Pharmaceuticals which is an independent office under the State Council.,

Canada has set up the Patented Medicine Prices Review Board which ensures that the prices of patented medicines are not excessive. The board is an independent autonomous and quasi-judicial body and the Government has no power to direct it. The board determines if the price is excessive by applying the reasonable relationship test, the therapeutic class comparison test, the international prices comparison test or by comparing the change in prices with the change in the consumer price index over a specified period"

6.13 When the Committee enquired about the criteria for deciding the drugs to be included under price control or keeping them out of it, the Department of Chemicals & Petrochemicals submitted the following details:-

"The criteria are:-

(i) The criterion of including drugs under price control will be the minimum annual turnover of Rs. 400 Lakhs.

(ii) Drugs of popular use, in which there is a monopoly situation will be kept under price control. This purpose if for any bulk drug, having as annual turnover of Rs. 100 lakhs or more, there is a single formulator having 90% or more market share in the Retail Trade (as per ORG) a monopoly situation would be considered as existing.

(iii) Drugs in which there is sufficient market competition viz. at least 5 bulk drug producers and at least 10 formulators and none having more than 40% market share in the Retail Trade (as per ORG) may be kept outside the price control. However, a strict watch would be kept on the movement of prices as it is expected that their prices would be kept in check by the forces of market competition. The Government may determine the ceiling levels beyond which increase in price would not be permissible.

(iv) Government will keep a close watch on the prices of medicine which are taken out of price control. In case, the prices of these medicines rise unreasonably, the government would take appropriate measures, including reclamping of price control.

(v) For applying the above criteria, to start with, the basis would be the data upto 31st March 1990 collected for the exercise of the Review of the Drugs Policy. The updating of the data will be done by the National Pharmaceutical Pricing Authority.

(vi) Genetically engineered drugs produced by recombinant DNA technology and specific cell/tissue targeted drugs formulations will not be under price control for 5 years from the date of manufacture in India.

Manufacturers of price control drugs are allowed a post tax return of 14% on net worth or a return of 22% on capital employed or in respect of new plant on internal rate of return of 12% based on long term marginal costing depending upon their option.

Document 3

SUMMARY AND RECOMMENDATIONS[3]

6. The group constituted by the committee to consider an appropriate methodology has made the following suggestions, with which the committee agrees:

(i) The minimum MAT value of a brand for the purpose of determining the mass consumption nature of the drug may be considered as Rs. 10 crores.

(ii) Secondly, a brand with 10 percent or more share in a given category may be treated as having inadequate competition.

(iii) Identify the brands having MAT value of Rs. 10 crores and above with a share of 10% or above in the group/category (there are approximately 180 categories in ORG). For this purpose, the March 1999 issue of the ORG-MARG Report which provides firm data for the year, 1998-99 be used.

(iv) Exclude all brands having Ayurvedic and other products which are not covered under DPCO.

(v) Exclude the multi-ingredient based brand formulations

(vi) List out the bulk drugs contained in each of the brand products so selected for the purpose of identifying the bulk drugs to be included under price control.

(vii) From the list of bulk drugs so worked out, the low cost drugs may be eliminated on the basis of "per day cost of a medicine" worked out based on the maximum retain price (MRP) of the top selling pack of the brand from which the concerned bulk drug was identified. As stated earlier, the per day cost of a medicine should not exceed Rs. 2.00 for being considered as "low cost medicine".

7. The committee recommends that the above methodology be adopted for identification of specific bulk drugs to be put under price control. Accordingly, the Government would need to undertake an exercise to arrive at a list.

[3] Reproduced from *Report of the Drug Price Control Review Committee*, Dept of Chemicals and Petrochemicals, New Delhi, October 1999. Extracts from Chapter VI of the Report.

Document 4

Price trends of Some Top Selling Drugs (In the Group/sub-group)
Period: January 1995 and June 1999)[4]

S. No.	Product Name	Company	Pack Size	Group Name	Price Rs. Jan.95 (as per ORG)	Price Rs. June 99 (ass per ORG)	% change
1	Strepsils	Boots	8's	Cough & C old	1.03	6.13	495.15
2.	Pyridium	Parke Davis	10's	Urinery Antiseptic	4.02	18.71	365.42
3.	Mikacin	Aristo	2ml/ 500mg	Antibiotic	13.32	47.49	256.53
4.	Vicks Inhaler	Procter	1's	Inhalents	4.51	15.86	251.66
5.	Domstal	Torrent	30ml	Anti Hystamine	5.32	18.62	250.00
6.	Vibazine	Medibios/P ZR	8's	Antibiotic	16.05	48.53	202.37
7.	Cephaxin	Biochem	1gm	Antibiotic	47.00	135.23	187.72
8.	Fifol-Z	SBP	30's	Anti Anaemics	15.48	42.95	177.45
9.	Vick Action 500	Procter	8's	Anti Cold	3.42	8.31	142.98
10.	Daflon-500	Serdia	10's	Vasoprotec tives	50.96	120.13	135.73
11.	Stibanate	Gluconate	30ml	Anti parasitic	30.24	66.50	119.91
12.	Isokin	Parke Davis	300mg/ 10's	Anti TB	2.63	5.78	119.97
13.	PZA Ciba	Novartis	750mg/ 10's	Anti TB	22.48	42.66	89.77
14.	Banocide	Glaxo	10's	Anti Filarals	1.56	2.94	88.46
15.	Zandu Balm	Zandu	10gm	Rubs & Pain Balms	5.85	10.85	85.47
16.	Perinorm	IPCA	10's	Anti Emetics	4.00	7.29	82.25
17	Daonil	Hoechst	5mg/	Anti	2.64	4.78	81.06

[4] Reproduced from Table 5.3, *DPCRC Report*, 1999, page 93.

			10’s	diabetic			
18	Combutal	Lupin	800mg/ 10’s	Anti TB	15.21	26.72	75.67
19	Broadicillin	Alkem	1 Vial/ 500mg	Ampicillin Injectable	8.26	13.07	58.23
20	Tenoric	IPCA	10’s	Hypotensive with Di	10.75	16.31	51.58

Difference in prices of formulations based on same bulk drugs[5]

S. No.	Manufacturers	Formulation/Proudct	Composition	Pack	MRP	Batch No.	Date
1	Pfizer	Vicon 250mg	Azythomycin Cap	6's	233.38	820-64001	May 98
2	Alembic	Abithral	Azythomycin Cap	6's	143.40	81007	June 98
3	Pfizer	Amloged 5mg	Amlodipine Besylate	10's	47.82	820.05008	June 98
4	Intas Pharma	Amtas-5	Amlodipine Besylate	7's	9.00	8006	June 98
5	Unichem	Ampoxin 500	Ampicillin250 Cloxacillin 250	10's Al/St	42.92	BB8986	July 98
6	Glaxo	Fortum 1 gm Inj.	Ceftaridine	1gm	341.92	N634	June 98
7	Lupin	Tirime	Ceftaridine	1 gm	299.00	72001	May 97
8.	Pfizer	Magnamycin Inj.	Cefopersason Sod. USP	1 gm	265.14	80735054	March 98
9.	Panacia	Myficef	Cefoperason Sod. USP	1 gm	170.00	LD4022	Dec. 97
10	Johnson & Johnson	Risperdal	Resperiodone 1 mg	10's Al/St	127.35	006	3/98
11	Torrent Pharma	Respidon	Resperiodone 1mg	10's	18.55	BN1001	Apr. 97
12	Protecter	Risnia-1	Resperiodone 1 mg	10's	7.00	A70299	Sep. 97
13	Glaxo	Cetrizine	Ceterizine 10mg	10's	26.70	1037	Aug 98
14	Lupin	CZ-3	Ceterizine 10mg	10's	7.70	8087	08/98

[5] Reproduced from Table 5.4, *DPCRC Report*, 1999, p.94.

Difference between wholesale price and MRP (%)[6]

S. No.	Company	Drug	Packing	Wholesale Price (Rs)	MRP (Rs)	Margin (%)
1	Wings Pharmaceuticals	Tetracycline Caps 250 mg 10 x 10	10 x 10	52.11	130.00	150.00
2	____Generics	Inj. Dexa____ Sod. Phos	10ml vial	11.75	33.00	181.00
3.	Ind. Swift Ltd.	Inj. Gentamuycin (as sulphate) 60mg/2ml	10ml vial	10.89	25.00	130.00
4	Ind. Swift Ltd.	Switax 500mg (cofetoxlime Sod)	Vial	24.81	50.00	101.00
5	Ind. Swift Ltd.	Amyclox 500 (Amoxycillin 250mg+ Ciprollox 500mg	10 x 10	296.45	710.00	139.00
6	Max India Ltd.	Ciprollox 500mg	10 x 10	235.00	616.00	182.00`
7	Max India Ltd.	Tetracyucline 250mg Cap	10 x 100	620.00	109.12	76.00
8	Max India Ltd.	Inj. Cefatoxime	Vial	38.25	80.32	110.00
9	Wockhardt	Inj. Gentamycin	10ml vial	9.78	30.00	206.00
10	Wockhardt	Cap. Ciprollaxcin 250 mg	10 tab	13.09	53.00	305.00

[6] Reproduced from Table 5.6, *DPCRC Report*, 1999, p.95.