

**How Effective Is
India's Drug Price Control Regime?**

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Introduction

Currently India's ascendancy as a 'global pharmacy' for low and middle-income countries cannot be disputed. From a situation of net-importer in the pre-1970 era, India is now currently a net-exporter of quality and cheap generic drugs across the world.¹ Both in terms of bulk drugs and formulations production, India's drug manufacturing capacity and its capability to 'reverse engineer' is considered to be one of the top among developing economies.² However, due to a crumbling and dilapidated public health care system, most of the drugs are either out of stock or the system simply do not have adequate resources to buy them. This has largely resulted in private sector takeover of health care system in the country. Due to this development, households' are increasingly paying out-of-pocket (OOP) for the purchase of health care and more so for drugs.³ India hardly has any social insurance cover to its over one billion population.⁴ Moreover, the private voluntary insurance sector, whose contribution is around half a percent of the

¹ The estimated size of India's pharmaceutical industry is about US \$ 11,120 million in 2004-05. While formulations account for 78 percent and the rest 22 percent is accounted for by bulk drugs. In volume and value terms, it ranks fourth and thirteenth position respectively in the global market. (Source: Government of India 2006). As far bulk drugs are concerned, India's position is 4th in the international market and is estimated at about US \$ 3.29 billion (Source: Cygnus Business Consulting Research, May 1, 2007).

² Over two-thirds medicines manufactured in India are exported to developing countries. It is estimated that around half of all essential medicines distributed by UNICEF in developing economies originate from India while nearly 80 percent of Zimbabwe's public sector health facilities tender purchase of drugs are procured from Indian producers. See MSF <http://www.accessmed-msf.org/documents/Overview%20Jan%202007%20FINAL.doc>

³ See Sakthivel (2005).

⁴ Roughly two and half percent of the population are covered by social health insurance, such as, CGHS (Central Government Health Scheme) and ESIS (Employees State Insurance Scheme). See Govt. of India (2005a).

health care market, excludes drug reimbursement from its coverage. Hence, a substantial proportion of population is largely exposed to the drug market whose purchasing power is extremely low.⁵

Regulation of Drug Market

Across the globe drug prices are in one way or the other subject to controls and regulations (Henry & Lexchin, 2002). A host of policy instruments are exercised to rein in drug price from increasing to unreasonable level. Such controls take the following forms in single or in combination of more than one instrument: cap on mark-ups, fixed margins to wholesalers/pharmacists, price freezes, reference pricing, ceiling on promotional expenditure, differential value added tax on drugs, etc.

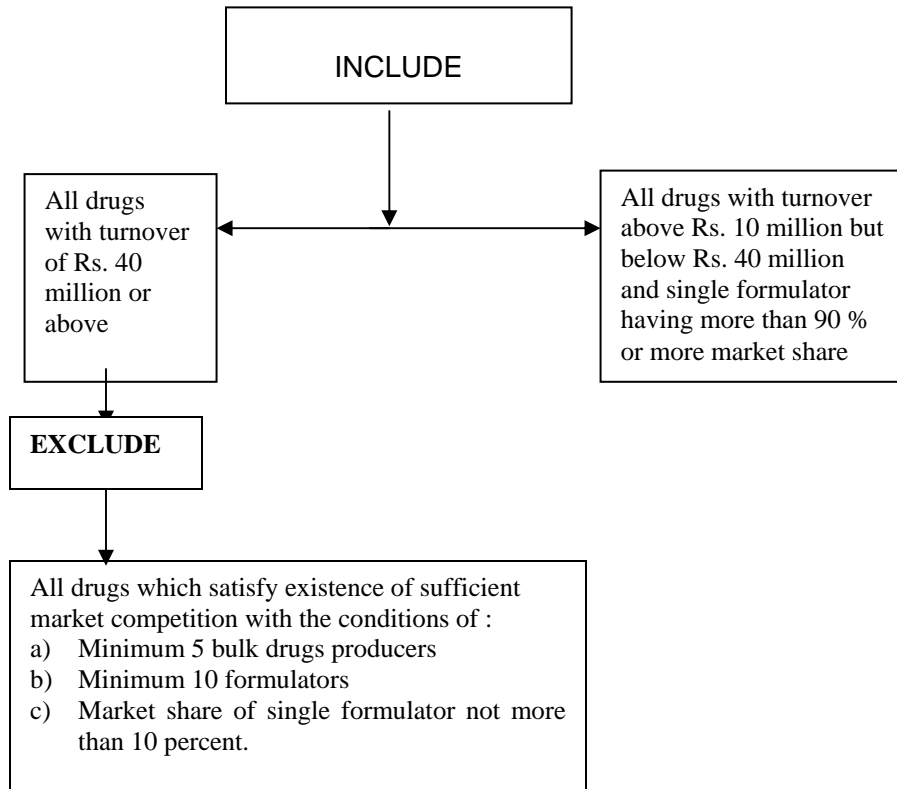
Prices of drugs in India were once considered to be one of the highest in the world (Govt. of India, 1975). The trend of high prices has tended to reverse since the 1970s in the wake of a series of policy measures, such as, drug price control, process patents for drugs, etc (Govt. of India, 2005b).

Over the years, however, price controls are being dismantled gradually and the number of bulk drugs that were under price control has been brought down gradually to a very minimum level. In 1979, 347 bulk drugs were under the price control, which came down to 166 in 1987 and further reduced to 142. Drastically pruning the list of drugs under control further, the Drug Price Control Order (DPCO) of 1995, sought to limit the control to just 76 drugs. The DPCO delineates certain benchmarks on which price control is based. These are i) sales turnover, ii) market monopoly and iii) market competition.

⁵ India's per capita GDP per annum for the year 2005 stood at US 730 (See World Bank Country Profiles) while per capita health spending is a paltry US 27 during the same period (See World Health Report, 2007, WHO).

Chart 1

Criteria for Inclusion of Drugs Under Price Control, DPCO, 1995



Source : Government of India (1999), Report of the Drug Price Control Review Committee, Department of Chemicals and Petrochemical , October, New Delhi

Notes : i) Bulk drug turnover includes local production and import values

ii) A formulator is a manufacturer of single ingredient formulation containing the subject bulk drug

iii) Market share of single formulator of single ingredient formulation of the subject bulk drug marketed in the country (as per Operations Research Group, ORG)

iv) Reference for the market share determination is data reported in ORG, March, 1990

In effect, formulations that are under price control are those that have i) annual turnover of Rs. 40 million and above with monopoly scenario (see chart 1 for detailed criteria) and ii) annual turnover of less than Rs. 40 million but not less than Rs. 10 million with less market competition. Across the board, the price control order of 1995 fixed 100 per cent Maximum Allowable Post-Manufacturing Expenses (MAPE) to all drugs.

The retail price of the formulation is calculated based on the following formula:

$$\text{Retail Price} = (M.C + C.C. + P.M. + P.C.) X (1+MAPE/100) + E.D.$$

Where M.C denotes material cost including drug cost and other pharmaceutical aids; C.C. indicates conversion cost; P.M. means packing material cost of formulation; P.C. connotes packing of shipment; MAPE denotes Maximum Allowable Post-Manufacturing Expenses which includes trade margin and E.D. indicates excise duty.

The recent policy changes have enormous implications for drug prices in India. As of today, only one-tenth of drug market is price controlled as against nearly 90 percent during the late 1970s.⁶ This has triggered wide debate on the rising drug prices (Rane 1996 and Srinivasan, 1999). Rane (1996), who has been consistently analysing the drug prices over the years⁷ show that pharmaceutical price policy changes have led to a phenomenal increase in the price of drugs, of different therapeutic groups, during 1980 to 1995, surpassing the general index of prices. The genuineness of this concern and evidence can be seen *prima facie* in the sharply widening gap between general price index and pharmaceutical price index (Chart below). Trends in the index provides a clear evidence of sharp and significant rise in drug prices during 1993-94 to 2003-04. However, there is a need to study price trends in various therapeutic segments, since the

⁶ Govt. of India (2005b), Report of the Task Force to Explore Options Other Than Price Control for Achieving the Objective of Making Available Life-Saving Drugs At Reasonable Prices", September, 20, pp.17.

⁷ For an analysis of drug price in India over the years, see Rane (1990), (1992), (1993a), (1993b) and Srinivasan (1999).

overall pharmaceutical index does not capture all segments and moreover drugs cannot be treated as a single market but a multi-product one.

<<<Chart 2 about here>>>

Methodology

The analysis basically involves examining price trends of essential drugs that are part of DPCO, 1995 and those that are outside price control for the period spanning 1994 to 2004. The basis for delineating drugs under price control and decontrol are derived from the government list of drugs under control⁸. Further, from this list only essential drugs would be studied.⁹ The number of essential drugs examined for analysis therefore is as follows: i) 31 essential drugs (out of 142 drugs under DPCO, 1987) which went off price control in 1995 and ii) 33 essential drugs (out of 76 drugs under DPCO, 1995) under price control. Subsequently, the retail price of formulations involving each of these drugs was obtained from various issues of Monthly Index of Medical Specialities (MIMS), India spanning one decade from 1994 till 2004.

Although the number of products (formulations) considered initially was to the extent of 300 plus products, after elimination the number came to less than 100 products in each of price controlled and decontrolled products. Elimination of such a large number of products became imperative due to the following: i) for consistency, different dosages and strengths were ignored and only packs containing similar units, dosage forms and strengths were included; ii) care has been taken to exclude combination

⁸ See Government of India(1995), The Drugs (Prices Control) Order, 1995.

⁹ The list of essential drugs formulated by the government of India (National List of Essential Medicines, 2003) is similar to WHO List of Essential Drug List. The list contains 354 drugs, see Government of India, 2003.

products as this may yield distorted results, although total exclusion is not possible; iii) products that are not listed in MIMS India continuously for ten years are also ignored from the analysis. Depending upon the exclusion criteria underlined here, the number of formulations (products) considered varies in each therapeutic category.

Results

The price change during the period from 1994 to 2004 is captured by working out year-on-year percent change and cumulative ten year price change. The annual observed trend in price change could be deciphered from Charts 3 (a)-(d) and 4 (a)-(d), while annual cumulative percent price change in drugs is provided in Table 1 and 2. A relative examination of drug prices under control and decontrol throws up interesting results.

<<<Charts 3 (a)-(d) about here>>>

<<<Charts 4 (a)-(d) about here>>>

A general trend that emerges from the table clearly shows that drugs which are under price control have tended to be either stable or have shown a downward movement. Therapeutic category-wise analysis of annual cumulative percentage price change reveals that many of the essential drugs under each therapeutic class (over half of drugs considered for the analysis) have displayed negative price trend signifying price declines. For example, nalidixic acid (-7.17 percent), ranitidine hcl. (-7.44 percent), levodopa (-5.31 percent) are among the drugs that had shown substantial price decrease. All antibiotic preparations which are under price control witnessed negative price growth. The other drugs (with respective percent) whose prices have registered decline (negative price growth) during the period under consideration are furazolidone (-2.69), methyl

dopa (-1.41), carbamazepine (-0.11), chlorpromazine (-0.11), norafloxacin (-3.19), amikacin sulphate (-0.78), ciprofloxacin (-4.09), gentamicin (-1.13), tetracycline (-1.24), metronidazole (-1.21), rifampicin (-0.66) and salbutamol (-1.60).

Three segments which appear to have ducked the general trend are drug prices relating to anti-T.B. drugs (streptomycin), antimalarials (sulphadoxine) and topical steroid preparations (framycetin sulphate) whose prices have accelerated 4-6 percent annually.

<<<Table 1 about here>>>

We next move on to investigate the price trend witnessed during this period for those drugs that are price decontrolled in DPCO, 1995 but were part of controlled regime of DPCO, 1987. This probe assumes vital importance as the drug industry continues to claim that since the drug market is competitive, price rise can be checked by market forces. Does this stand scrutiny to facts? Figures put out in Table 2 shows the opposite. Unlike price controlled drugs, the general price trend of decontrolled drugs reveals that it had shown an upward movement. For the ten-year period spanning 1994 through 2004, price increase has been enormous across therapeutic groups. The rise is more pronounced in the following therapeutic categories with a double digit price rise: anti-diuretics, cardiac disorders, anti-allergic, peripheral vasodilators and antileptotics. To be specific, the segments that witnessed two-digit price rise are acetazolamide (18.76 percent), promethazine hcl (14.62 percent), digoxin (14.38 percent), isoxsuprine hcl (11.35 percent) and clofazimine (10.84 percent). Gentamycin in the class of antibiotics seem to have been the only exception, which had shown a marginal downward slide

(-2.26 percent) and anti-fungal preparation led by Griseofulvin (0.35 percent) that displayed price stability.

<<<Table 2 about here>>>

To sum up, a comparative diagnosis of drug price trends (controlled and decontrolled) reveals the following:

i) Drugs under the segments such as the central nervous system, cardiovascular system, genito-urinary system, respiratory system and certain sub-categories of infections and infestations like antibiotics have very clearly established that the essential drug prices under control have either shown a constant price behaviour or have even declined in many categories (reflected in negative price percentage). It is to be noted there are few exceptions to the price trends witnessed in this category. For instance, streptomycin, pentazone, frusemide and framycetin sulphate experienced nearly six percent annual price rise while couple of other formulations also witnessed 3-4 percent increase per annum. This could probably be attributed to the fact that the present system allows a permissible price rise of upto 20 percent per annum in few exceptional cases and the companies must have exercised this option.

ii) However, on the other hand, essential drug prices that are now decontrolled have generally tended to move upwards marginally or in certain cases more sharply. This is revealingly captured in Charts 1 and 2. There are few products that experienced negligible rise in price of less than one percent, such as, gentamycin, neomycin, ampicillin, neomycin and timolol maleate. Presence of large number of players in this generic market could have played a major role in stemming price rise.

iii) The maximum price rise was observed in the category of anti-allergic disorders both under controlled and decontrolled price regime. iv) The other interesting trend that emerges from the analysis is that drug price decline under controlled regime has been albeit modest whereas drug price rise under decontrolled policy environment is exceedingly high.

Discussion

Drug price plays a significant role in the access to medicines, particularly in low income country with virtually private dominance of health service provision and financing with a near absence of social health insurance system. Drugs and medicines form substantial portion of households' out-of-pocket spending in developing countries. While households' in low-income economies spent an estimated 71.6 percent of all pharmaceutical spending, the respective share of households' in high-income countries is only 57.8 percent¹⁰. Estimates derived from National Sample Survey (NSS), India for the year 1999-00 suggests that over 12 percent of the non-food consumption expenditure of households went into health spending. Estimates further shows that while 70 percent of the households OOP health expenditure in urban India went into buying drugs, in rural India, however, the share was as high as 77 percent.

Like any other commodity markets, pharmaceutical sector is also being subject to liberalization process in India. All non-tariff barriers to drug imports are abolished and substantially axed the scope of industrial licensing. Moreover, foreign direct investment in the drug sector is now 100 percent allowed while the earlier provision of allowing only

¹⁰ See WHO (2004a), World Medicine Situation, pp. 46

public sector companies to produce five essential drugs also stands cancelled. According to the Pharmaceutical Policy of India 2002, drug prices were to be decontrolled by half of the remaining 74 drugs (Government of India, 2002). Due to litigation in various state courts initiated by the drug companies and by consumer groups, the Pharmaceutical Policy of 2002 was stalled from being implemented.

During the pre-1970s period drug prices in India were at par with global prices. In the last three and half decades, the trend of high drug price has reversed positioning the country with an unenviable record of lowest medicine prices in the world. This is made possible by few policy initiatives by the earlier progressive governments: i) a shift away from product to process patent regime in 1970; ii) drug price control order (DPCO), 1970 and iii) anti-competitive and anti-monopoly acts such as, FERA (Foreign Exchange Regulation Acts) and MRTP (Monopoly Restrictive Trade Practices) Acts. These policy interventions had curbed the role and significance of transnational drug corporations. Domestic drug companies are now capable of indigenously producing both bulk drugs and formulations to a large extent while drug prices today are relatively one of lowest around the globe.

Setting relatively lower prices is made possible in the Indian context because of direct price control along with process patent regime, which in turn actively played the role of introduction and diffusion of new drugs by mushrooming growth of new companies in the multi-therapeutic drug market. However, drug companies have been vociferous in the past seeking dismantling of the existing price control regime. The pharmaceutical companies, both multinational and domestic ones, argue that price control affect their bottom line in terms of reduced profit. Further, the multinational drug

companies also attribute the existing price control regime to slow introduction of new drugs in India. But available evidence on both counts show the opposite. Drug companies in India reflecting global trends, have registered super-normal profits consistently in the last two decades as compared to other commodity sectors. This is true of whatever criteria that one wants to look at – Gross Profits to Sales, Profit After Tax to Net Worth, or Return on Capital Employed (ROCE) (Sakthivel 2001; Economic Times 2001). Similarly, relative to other developing countries, India's market is awash with new products and the gap between global introduction of new drugs and its entry as generic versions in India has not only narrowed over the years but it is extremely rapid.¹¹

The change over to a stringent patent regime is likely to place many segments of drug prices to international price levels leading to out of reach for broader sections of society.¹² One of the sensitive and a highly controversial issue in regard to TRIPS under WTO is the concern about the high price of medicines. Several studies in the Indian context, mostly of simulation exercise carried out by Fink (2000), Watal (2000) and Chaudhari, S. et.al (2003) all clearly show the extent of price increase and loss of consumer welfare that would likely to result in near future with change over from the earlier process patent system to a patent monopoly era. In fact, India's changeover to product from process patent era is likely to endanger a critical source of access to

¹¹ According to IMS-ORG (2004), new launches of drug products in India for the year during 2002-2004 constituted eight percent of the total market.

¹² The recent controversy surrounding Glivec, a cancer drug used to treat chronic myeloid leukemia patented by Novartis in India is a cause for major concern among patient groups. The drug is marketed by Novartis in India at around US \$ 26,000 per annum as against one-tenth of its price offered by Indian domestic generic companies. See Mueller, 2007.

lifesaving generic medicines not only in India but around the world (Baker 2007; MSF 2007; Grace 2004).

The sharp rise in drug prices could also result from high and growing trade margins. It must be noted that not only there is a general rise in pharmaceutical prices, the initial price *per se* is fixed with enormous margins. Trade margins are one of the highest in the pharmaceutical industry (Sakthivel 2005 and Srinivasan 1999). Add to it, the extra sales taxes levied by respective state governments – since drugs come under state subject. Local sales taxes differ from one state to another. The extent of exorbitant trade margins is shown to be jacking up drug prices. A study by Sakthivel (2005) and Srinivasan (1999) shows that tender purchase of drugs by Tamil Nadu Medical Services Corporation (TNMSC), a state-government level drug procurement agency, has revealed post-manufacturing margins running into four digit levels in retail purchase while in tender purchase the prices were at rock bottom¹³.

It is often argued that India's drug market is a competitive one with nearly 10,000 companies competing in various therapeutic segments. This is said to have kept the drug price at low level. However, it is highly a contestable claim while evidence seems to suggest that there is high market concentration (Chaudhary 2002; Sakthivel 2005; Sen). India's drug market appear to mimic the world's pharmaceutical market wherein in many of the therapeutic segments, three to four companies together account for over 60-70 percent of the market. It needs no reiteration that consumer sovereignty simply does not exist in the pharmaceutical market. Since the consumers' demand is essentially supply-

¹³ See Srinivasan, S (1999), "How Many Aspirins to the Rupee? Runaway Drug Prices", Economic and Political Weekly, February 27-March 5.

driven (supplier-induced demand) in the pharmaceutical market, the physician or the pharmacist has no incentive to be price-sensitive (Fuchs 1986; Labelle, et al. 1994).

The emergence of Indian domestic companies in the international arena as cheap and quality generic medicine suppliers has its own dynamics of affecting domestic prices. This is likely to happen since domestic prices are to be aligned with global export prices which will ultimately affect a substantial share of the population. “Only companies who see their future as being inextricably linked to the domestic market will retain sensitivity to the affordability issue” (Government of India, 2005b). In addition, affordability issue may take back seat in the backdrop of product patent regime given global reference pricing issue involved. Any New Chemical Entity (NCEs) that will be introduced in the Indian market by transnational drug companies in future will pitch initial price at higher level reflecting global reference pricing.

Emerging Policy Issues

Drug price plays a vital role in access to essential medicines across the world. It assumes critical importance in low-income economies since 70 percent of all health spending is accounted for by households while nearly 70 percent of all households' expenditure on health goes into procuring drugs. Therefore, an effective and overt price control on drugs is the need of the hour. While price monitoring could help to serve as a credible threat to price rise, price negotiation is useful as an initial step towards introduction of newly patented drugs at reasonable price. However, direct price control is the ultimate tool to stem price increase from breaching the roof. Although direct price control measure is useful in later stage after the introduction of newly patented drugs,

compulsory licensing would prove to be more effective in setting ‘blockbuster’ new drug prices at an affordable level.

In its present form, DPCO is ineffective as it is inadequate in its coverage and do not serve its purpose to a large extent. There is an urgent imperative to spruce up the existing criteria for price control. The present practice of using monopoly and market dominance measures need to be replaced with the criteria of ‘essentiality’ of drugs. This would have maximum spill-over effect on the entire therapeutic category. This is also likely to prevent the present trend of circumventing price controls through non-standard combinations and at the same time would discourage producers moving away from controlled to non-controlled drugs. Direct price control should be applied on formulations rather than basic drugs. This is likely to minimise intra-industry distortion in transaction.

Other than overt regulatory controls, accelerating access to drugs can also be ensured by way of shoring up the mechanism of bulk procurement of drugs. The success of this move is largely vindicated in few states in India which has become a role model in recent years. Huge trade margins are a rule rather than exceptions in Indian drug industry. In view of this, there is a need to fix ceiling on trade margins which could lead to significant downward influence on medicine prices. Finally, we argue that to ensure drug security in India, a strong regulatory institutions need to be established.

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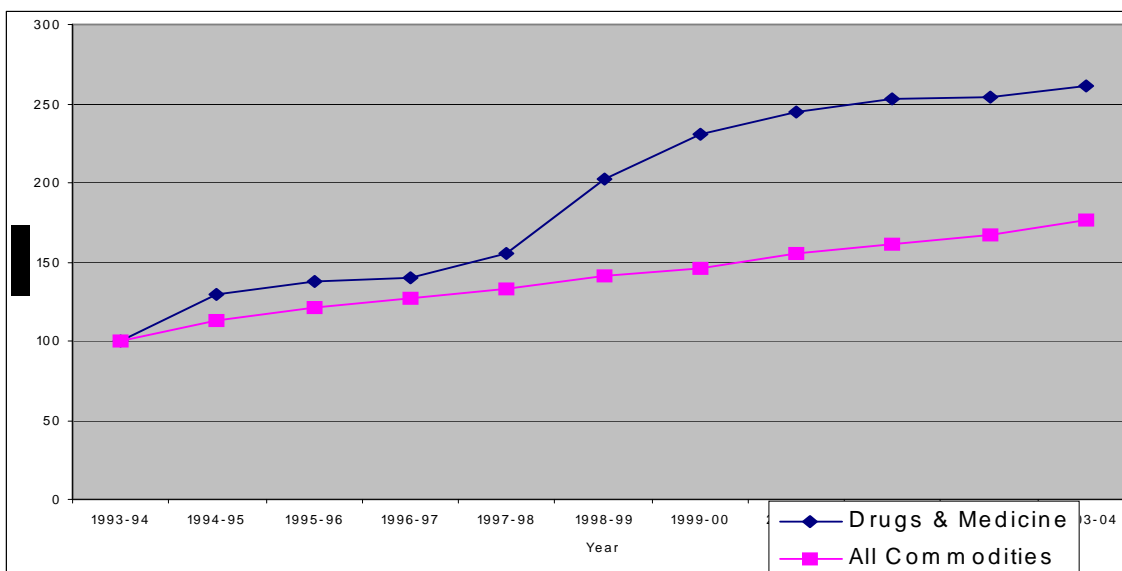
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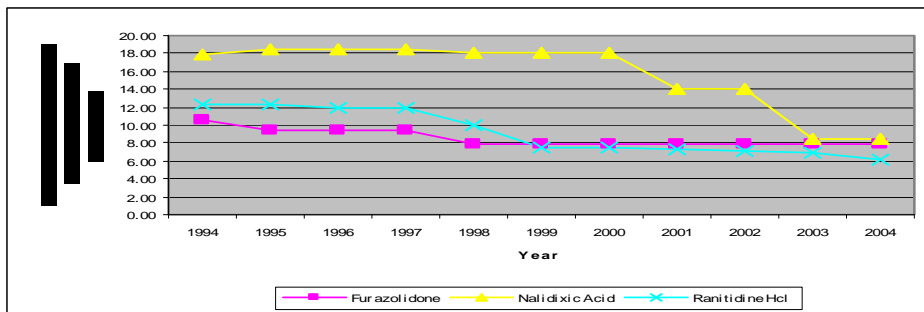
Chart 2
Trends in Pharmaceutical and All Commodity Price Index



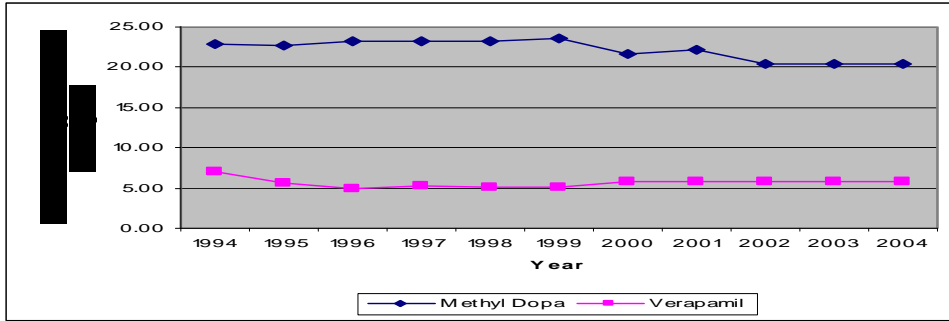
Source: Reserve Bank of India, Various Issues

Price Trends of Drugs Under Control, 1994-2004

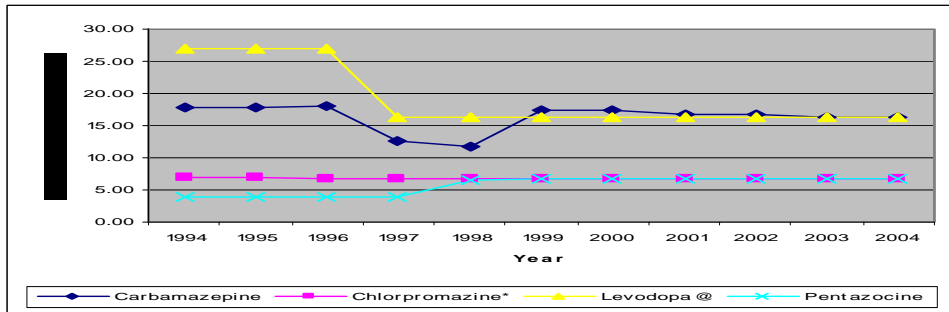
3(a) Alimentary System



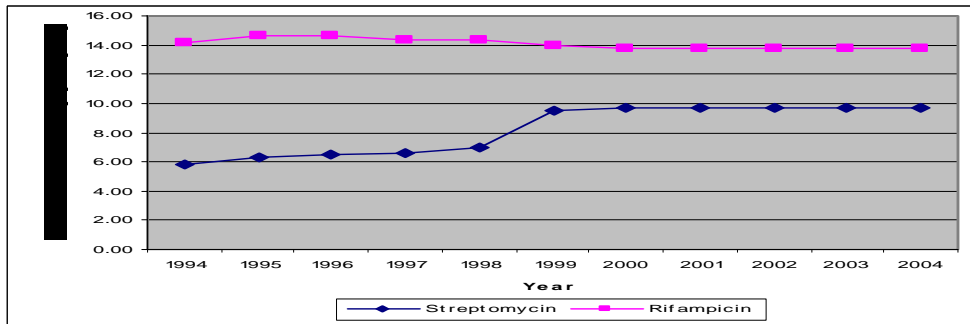
3(b) Cardio-Vascular System



3(c) Central-Nervous System

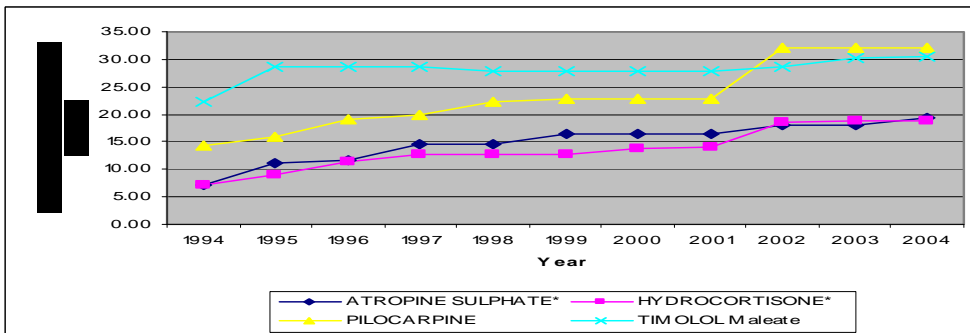


3(d) Anti-Tuberculosis

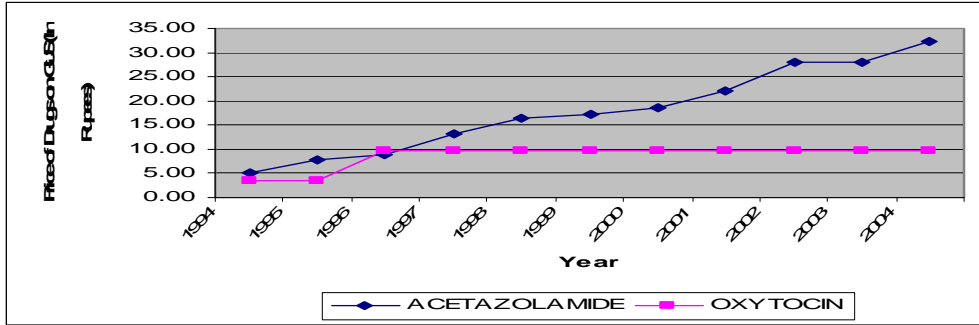


Price Trend in Decontrolled Drugs, 1994-2004

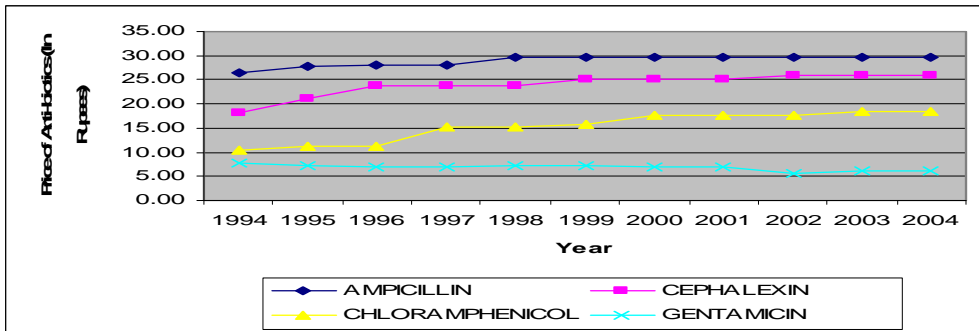
4(a) Drugs Relating to Eye Infections



4(b) Genito-Urinary System



4(c) Antibiotics



4(d) Anti-Tuberculosis

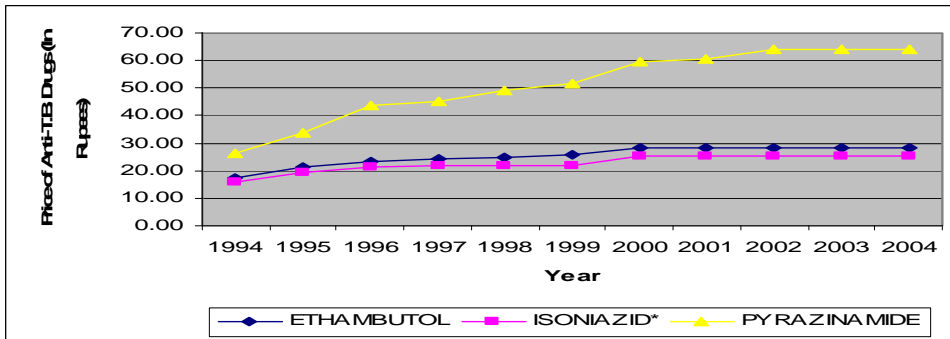


Table 1

Annual Cumulative Percentage Price Change

Therapeutic Categories	Drugs	1994-2004
Antidiarrhoeals	Furazolidone	-2.69
Antidiarrhoeals	Nalidixic Acid	-7.17
Gastro-intestinal Sedatives	Ranitidine Hcl	-7.44
Anti-allergic drugs	Pheniramine	1.11
Anti-hypertentives	Methyl Dopa	-1.41
Anti-hypertentives & Antianginals	Verapamil	0.04
Anticonvulsants	Carbamazepine	-0.11
Sedatives & Tranquillisers	Chlorpromazine	-0.11

Rigidity & Tremor Controllers	Levodopa	-5.31
Analgesics & Antipyretics	Pentazocine	6.62
Diuretics & antidiuretics	Frusemide	4.32
Urinary anti-infectives & anti-spasmodics	Norafloxacin	-3.19
Diuretics & antidiuretics	Spironolactone	3.78
Corticosteroids & related drugs	Dexamethasone	0.00
Hyper and Hypoglycaemics	Insulin	0.68
Corticosteroids & related drugs	Prednisolone	3.75
Antibiotics	Amikacin sulphate	-0.78
Antibiotics	Ciprofloxacin	-0.38
Antibiotics	Cloxacillin	-4.09
Antibiotics	Erythromycin	0.29
Antibiotics	Gentamicin	-1.13
Antiamoebics	Griseofulvin	0.35
Antituberculous Drugs	Streptomycin	6.09
Antimalarials	Sulphadoxine	4.29
Antibiotics	Tetracycline	-1.24
Antimalarials	Chloroquine	-3.33
Antiamoebics	Metronidazole	-1.21
Antituberculous Drugs	Rifampicin	-0.66
Non-Steoid Anti-Inflammatory Drugs	Ibuprofen	-1.67
Bronchospasm Relaxants	Salbutamol	-1.60
Bronchospasm Relaxants	Theophylline	1.42
Topical Steroid Prep.	Betamethasone valerate	1.21
Topical Steroid Prep.	Framycetin Sulphate	5.37

Table 2
Annual Cumulative Percentage Price Change

Therapeutic Category	Drugs	1994-2004
Aural Prep., Anti-inflammatory & anti-allergic prep., Topical Steroid Prep..	Neomycin	1.02
Anti-infective Prep.	Atropine Sulphate	8.09
Anti-inflammatory & anti-allergic prep., and Topical Steroid Prep.	Hydrocortisone	9.07
Glaucoma	Pilocarpine	8.17
Glaucoma	Timolol Maleate	1.63
Anti-allergic	Promethazine Hcl	14.62
Carcino-Chemotherapeutic drugs	Mitomycin-C	3.85
Antacids	Aluminium Hydroxide	4.16
Gastro-intestinal sedatives, anti-acid and ulcer	Metoclopramide	6.32
Antidiarrhoeals	Loperamide	9.36
Cardiac disorders	Digoxin	14.38
Peripheral Vasodilators	Isoxsuprine Hcl	11.35
Anti-hypertensives	Hydrochlorothiazide	2.06
Analgesics and antipyretics	Paracetamol	7.03

Antidepressants	Amitryptiline	5.02
Antidepressants	Imipramine Hcl	3.23
Anticonvulsants	Phenytoin	4.34
Diuretics and anti-diuretics	Acetazolamide	18.76
Drugs acting on the uterus	Oxytocin	8.92
Antibiotics	Ampicillin	1.00
Antibiotics	Cephalexin	2.79
Antibiotics	Chloramphenicol	6.17
Antibiotics	Gentamicin	-2.26
Anti-TB	Ethambutol	4.20
Anti-TB	Isoniazid	4.24
Anti-TB	Pyrazinamide	8.45
Antileprotics	Clofazimine	10.84
Antifungals	Griseofulvin	0.35
Anthelmintics & other anti-infestives	Diethylcarbamazine	8.06
Vitamins	Folic Acid	4.75
Expectorants, cough suppressant,etc.	Chlorpheniramine Maleate	5.68