

Access to Essential Drugs and Medicine

IN DEVELOPING COUNTRIES, HEALTH CARE HAS BEEN A NEGLECTED ISSUE IN the overall policy framework. With low public budgets, providing a universal social security cover to the population is difficult. On the other hand, households spend a sizeable portion of their income on food items, leaving little for health care.

The single most vital component of health care is drugs, as they account for a substantial part of household health expenditures. The market for drugs, particularly the allopathic category, has been growing rapidly in India—in terms of production, trade, investment and employment. However, the industry is characterized by supplier-induced demand (and therefore loss of consumer sovereignty), uncertain demand for the patients, oligopoly elements, monopoly profit, etc. This has far-reaching implications on the health care of the masses, whose essential problem lies in lack of purchasing power, lack of access and knowledge of modern medicine.

In view of the above, the specific objectives analysed in this chapter are the following:

- 1) Provide an estimate of drug expenditure patterns of both the government and households across States;
- 2) Examine the pattern of drug production;
- 3) Investigate whether the Indian drug industry is highly concentrated across therapeutic classes;
- 4) Assess the price change in drugs over the years, under different policy regimes;
- 5) Examine issues relating to drug regulation;
- 6) Critically evaluate public procurement of essential drugs, needed for the public health system;
- 7) Examine the impact of the patent regime since the 1970s and the likely consequences of Trade-Related Intellectual Property Rights (TRIPS) in the post-2005 period;

Analysis of state-wise drug expenditure in India

Share of household expenditure on drugs and medicines

Drugs and medicines form a substantial portion of out-of-pocket spending on health among households in India. Estimates from the National Sample Survey (NSS) for the year 1999–2000 suggests that over 5% of the total consumption expenditure of households went into health spending. However, there are significant variations among different categories of the population. For instance, Table 1 shows that the share of health in the total expenditure of households in rural areas is little over 6%, while that for urban India is little less than 5%. An analysis across States indicates that Kerala, which is one of the highly advanced State in terms of health indicators, spends a relatively larger share of household expenditure on health, both in rural and urban areas. Bihar and Assam, which are the poorest States in the country, spend relatively less. Table 2 depicts annual out-of-pocket health expenditure across states in India during 1999–2000.

Household drug expenditure in India

Estimates from the 55th consumption expenditure survey reveal that three-fourths of the total out-of-pocket (OOP) health expenditure is spent on drugs, in rural and urban areas. Tables 3 and 4 show that drug spending is high in lesser-developed States

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Table 1**Share of health to total household expenditure**

State	Rural	Urban	(in %) Aggregate
Andhra Pradesh	6.56	4.13	5.60
Assam	2.47	4.04	2.83
Bihar	4.40	2.96	4.15
Delhi	4.57	3.34	3.40
Goa	4.28	5.16	4.76
Gujarat	5.03	4.22	4.63
Haryana	6.99	6.56	6.84
Himachal Pradesh	5.25	3.91	5.04
Jammu and Kashmir	2.90	3.61	3.12
Karnataka	4.58	4.17	4.37
Kerala	7.79	7.15	7.59
Madhya Pradesh	6.05	5.25	5.74
Maharashtra	7.50	5.98	6.59
Orissa	5.46	4.51	5.24
Punjab	7.66	5.60	6.87
Rajasthan	4.79	4.70	4.76
Tamil Nadu	5.80	4.45	5.02
Uttar Pradesh	8.20	5.64	7.45
West Bengal	4.64	4.84	4.73
All India	6.05	4.91	5.57

Source: Extracted from the Unit-level Records of Consumer Expenditure Survey, 55th Round of NSS, 1999–2000

Table 2**Annual household out-of-pocket health expenditure (1999–2000)**

(Rs in crore)

State	Rural	Urban	Aggregate	GSDP/GDP	% to GDP/GSDP
Andhra Pradesh	2105	872	2976	125236	2.38
Assam	301	143	444	29263	1.52
Bihar	1609	234	1842	72083	2.56
Delhi	51	706	757	52914	1.43
Goa	35	51	86	6749	1.28
Gujarat	1065	882	1948	106427	1.83
Haryana	901	452	1353	48270	2.80
Himachal Pradesh	262	37	299	11983	2.50
Jammu and Kashmir	182	104	286	13961	2.05
Karnataka	1008	907	1915	96179	1.99
Kerala	1834	763	2597	62514	4.15
Madhya Pradesh	1418	790	2207	99322	2.22
Maharashtra	2639	3154	5793	241410	2.40
Orissa	781	198	979	36283	2.70
Punjab	1135	522	1656	62361	2.66
Rajasthan	1413	654	2067	80019	2.58
Tamil Nadu	1343	1430	2773	126500	2.19
Uttar Pradesh	6323	1804	8127	187641	4.33
West Bengal	1516	1222	2738	127933	2.14
All India	27280	15576	42856	1761838	2.43

Note: Applied per capita figures to mid-year survey population of Census
Source: Extracted from the Unit-level Records of Consumer Expenditure Survey, 55th Round of NSS, 1999–2000

(except Himachal Pradesh) such as Orissa (90.56%), Bihar (88.26%), Rajasthan (87.67%), Jammu and Kashmir (87.09%) and Himachal Pradesh (87.14%). Economically advanced States such as Maharashtra, Gujarat, Tamil Nadu and Karnataka reportedly spend less.

Estimates further show that out of per capita expenditure of households amounting to Rs 577 spent annually on health in urban India, Rs 400 goes into buying drugs, accounting for around 70%. In rural India, however, the share was 77%, while the spending pattern has been Rs 380 and Rs 295, respectively. Kerala, Haryana and Goa—all small States, appear to be spending over Rs 600 per annum per capita in urban areas while households in poor States such as Bihar and Orissa spend relatively less. Tables 5 and 6 further indicate that out of Rs 400

Box 1**Household health spending in India: Key statistics**

- In 1999–2000, 5% of total household consumption expenditure went into health spending; drugs accounting for the bulk of 4%.
- Rural households spend over 6% and urban households 5%.
- Kerala (4% of GSDP) is at the top of the spenders' list while Bihar and Assam incur relatively less (<1% of GSDP).

Box 2**Household drug expenditure**

- Household drug spending is high in less developed States—Orissa (90.64%); Bihar (89.14%); Rajasthan (89.43%); Jammu and Kashmir (90.39); while
- Advanced States spent less on drugs—Maharashtra (68.75%); Gujarat (63.90%), Karnataka (68.75%) and Tamil Nadu (61.41%).
- Urban India spends around 70% of OOP expenditure on drugs and 77% in rural India.
- In India, the share of drugs in total outpatient treatment is 83% in rural and 77% in urban areas.
- In India, the share of drugs in total inpatient treatment is 56% in rural and 47% in urban areas.

Box 3**Government budget expenditure on drugs**

- Approximately Rs 2000 crore incurred by both the Central and State Governments during 2001–02.
- The share of drugs in the health budget in the Central Government is around 12%.
- Southern States incurred the highest expenditure, with Kerala and Tamil Nadu spending around 15% each.
- Assam, Bihar, Uttar Pradesh and Orissa spent about 5% or less on drugs and medicines.

Table 3

Share of drugs in inpatient and outpatient expenditure of rural households (in %)

State	Inpatients		Outpatients		Share of Drugs in OOP
	Drugs to Inpatients	Inp to OOP	Drugs to outpatients	Out to OOP	
Andhra Pradesh	52.66	24.06	78.68	75.94	72.42
Assam	46.31	28.66	80.42	71.34	70.65
Bihar	68.46	11.48	91.83	88.52	89.14
Delhi	67.02	15.17	60.90	84.83	61.83
Goa	58.72	24.26	85.75	75.74	79.19
Gujarat	44.11	35.29	74.69	64.71	63.90
Haryana	41.45	25.90	89.16	74.10	76.80
Himachal Pradesh	68.94	25.37	95.76	74.63	88.96
Jammu and Kashmir	77.78	11.76	92.07	88.24	90.39
Karnataka	50.18	26.31	75.39	73.69	68.75
Kerala	49.42	34.21	83.48	65.79	71.83
Madhya Pradesh	67.53	20.52	84.83	79.48	81.28
Maharashtra	52.92	26.70	74.52	73.30	68.75
Orissa	78.88	15.88	92.86	84.12	90.64
Punjab	53.62	23.96	87.62	76.04	79.47
Rajasthan	71.99	20.75	93.99	79.25	89.43
Tamil Nadu	40.45	25.67	68.65	74.33	61.41
Uttar Pradesh	70.25	13.09	89.25	86.91	86.76
West Bengal	58.72	17.55	75.91	82.45	72.89
All India	56.04	21.52	83.17	78.48	77.33

Source: Extracted from the Unit-level Records of Consumer Expenditure Survey, 55th Round of NSS, 1999–2000

spent on drugs in urban India, a substantial part of it is by way of outpatient payments totalling around Rs 325 and the remainder (about Rs 75) is on account of inpatient payments. A similar pattern can be observed in rural India. Out of the total of Rs 295 spent on drugs annually, inpatient expenses accounted for Rs 45, and outpatient expenses were about Rs 250.

Results from the 55th National Sample Survey (NSS) consumption expenditure survey also reveal that the share of drugs in total outpatient treatment is extremely high. In rural India, the share of drugs is observed to be the highest, accounting for nearly 83%, while in urban India, this worked out to 77%, as depicted in Tables 2 and 3. In fact, in a few states, the share of drugs is more than 90% (Bihar, Himachal Pradesh, Jammu and Kashmir, Orissa and Rajasthan in rural areas and Haryana and Orissa in urban areas). On the other hand, the share of drugs in inpatient treatment is not as high as in the outpatient category. The respective share of drugs (inpatient) in rural and urban India was roughly 56% and 47%.

It is interesting to note that in rural India, if both inpatient and outpatient expenses are taken together, the share of drugs to total household expenditure accounts for roughly around 5% while in urban India, it is around 3.5%. Overall, as indicated earlier, it appears that little over 4% of the OOP spending of households goes into buying drugs.

Table 4

Share of drugs in inpatient and outpatient expenditure of urban households (in %)

State	Inpatients		Outpatients		Share of Drugs in OOP
	Drugs to Inpatients	Inp to OOP	Drugs to outpatients	Out to OOP	
Andhra Pradesh	40.20	19.67	78.99	80.33	71.36
Assam	45.13	27.35	77.29	72.65	68.49
Bihar	64.16	11.80	84.57	88.20	82.16
Delhi	57.72	37.09	81.52	62.91	72.69
Goa	58.07	34.29	82.12	65.71	73.87
Gujarat	50.34	30.02	77.80	69.98	69.56
Haryana	46.99	34.27	91.55	65.73	76.28
Himachal Pradesh	80.49	24.04	72.46	75.96	74.39
Jammu and Kashmir	62.07	23.55	87.26	76.45	81.33
Karnataka	39.27	32.70	64.07	67.30	55.96
Kerala	40.97	37.21	77.73	62.79	64.05
Madhya Pradesh	60.63	22.03	83.18	77.97	78.21
Maharashtra	48.21	30.18	63.78	69.82	59.08
Orissa	83.26	21.05	92.13	78.95	90.26
Punjab	31.89	26.22	88.83	73.78	73.90
Rajasthan	61.27	18.05	88.86	81.95	83.88
Tamil Nadu	36.63	31.63	72.92	68.37	61.44
Uttar Pradesh	59.61	17.00	85.95	83.00	81.47
West Bengal	39.18	22.72	76.21	77.28	67.80
All India	47.34	26.64	77.10	73.36	69.18

Source: Extracted from the Unit-level Records of Consumer Expenditure Survey, 55th Round of NSS, 1999–2000

Government expenditure on drugs

The magnitude of expenditure incurred on drugs by households does not show a similar pattern in public expenditure. The component of drugs and medicines in the overall budget of both the Central and State Governments is only a minor share, as salaries account for the bulk of the health sector expenditure in India. The analysis involves 16 major Indian States, which accounts for roughly 85% of the total health budget in the country.

The expenditure pattern on drugs of the State Government, as depicted in Table 7 shows that there are wide-ranging differences across States, from as little as less than 2% in Punjab to as much as 17% in Kerala during 2001–02. The southern States such as Kerala and Tamil Nadu spend over 15% of their health budget on drugs. Many backward States, both in economic and health indicator terms, incurred the lowest expenditure on drugs. States such as Assam, Bihar, U.P. and Orissa spent about 5% or less of their health budget on drugs and medicines.

It appears from the analysis that approximately Rs 2000 crore was spent in India by the State and Central Governments together on procuring drugs and medicines during 2001–02. The Central Government's share of drugs in its total health budget is around 12%. In all, roughly 10% of the health budget goes into procuring drugs in India.

Indian pharmaceutical sector: An overview

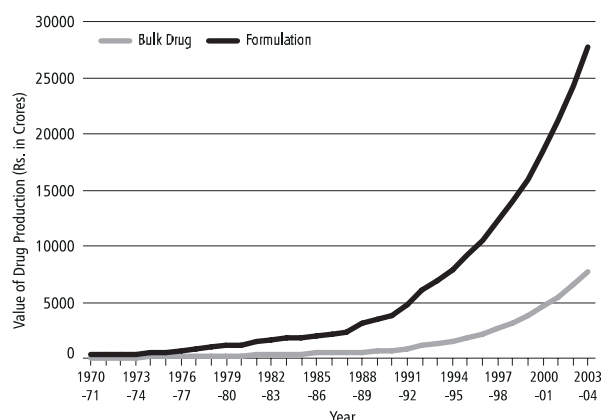
The pharmaceutical industry has witnessed tremendous transformation since the 1950s. The size of the Indian pharmaceutical industry, both bulk drugs and formulations is estimated at Rs 35,471 crore in 2003-04 (IDMA 2004), which is just over 1% of the global market (ICRA 1999). This is against the value of the production of pharmaceuticals of a mere Rs 10 crore in 1950 (Narayana 1984). At present, there are about 6,000 units operating in this sector (if only bulk drugs, formulations and large parenterals are taken into account) (Mashelkar Committee 2003). Investment in the industry has steadily grown over the years from a mere Rs 23.64 crore in 1950 to a moderate Rs 500 crore in 1980 and went up considerably to reach around Rs 4000 crore in 2003.

Propelled by the booming demand, the production of pharmaceuticals has registered a tremendous increase over the years. The growth rate of bulk drugs recorded in the 1970s and 1990s is almost double—around 20%—that of the production registered for the 1980s is evident from the Table 8. The output of formulations has seen a phenomenal increase during the period under consideration but is less than 4% as against bulk drugs, in both the 1970s and 1990s. The 1980s is the only period in which formulation growth had outperformed the growth of bulk drugs by a marginal 1%.

The massive growth of the pharmaceutical industry could be

Fig 1

Trends in the production of bulk drugs and formulations in India since the 1970s



attributed to a few domestic and international developments that took place particularly since the 1950s. At the global level, the industry in general was then experiencing a major overhaul by vertically integrating operations such as production, marketing and research. The protection given to the pharmaceutical industry through patents and brand names saw many top companies switch over to the production of specialty medicines.

Table 5

Percapita annual drugs and other medical expenditure (rural)

State	Inpatient		Outpatient		Aggregate	
	Drugs	Total	Drugs	Total	Total drugs	OOP
Andhra Pradesh	49.47	93.94	233.34	296.57	282.81	390.51
Assam	17.70	38.23	76.54	95.18	94.25	133.41
Bihar	17.00	24.83	175.86	191.52	192.86	216.35
Delhi	53.44	79.74	271.55	445.92	324.99	525.66
Goa	73.50	125.16	335.05	390.74	408.55	515.90
Gujarat	56.17	127.34	174.42	233.52	230.59	360.86
Haryana	67.06	161.81	412.81	463.01	479.88	624.83
Himachal Pradesh	86.09	124.87	351.80	367.39	437.89	492.26
Jammu and Kashmir	23.15	29.76	205.54	223.25	228.69	253.01
Karnataka	39.11	77.95	164.62	218.37	203.73	296.31
Kerala	134.07	271.31	435.63	521.82	569.70	793.13
Madhya Pradesh	43.14	63.88	209.94	247.49	253.07	311.37
Maharashtra	68.84	130.09	266.10	357.07	334.94	487.16
Orissa	32.16	40.77	200.56	215.99	232.72	256.76
Punjab	92.89	173.23	481.69	549.77	574.58	723.01
Rajasthan	51.21	71.14	255.45	271.78	306.66	342.92
Tamil Nadu	39.57	97.84	194.50	283.31	234.07	381.15
Uttar Pradesh	45.70	65.05	385.26	431.68	430.95	496.72
West Bengal	27.92	47.55	169.56	223.38	197.48	270.94
All India	45.91	81.93	248.53	298.83	294.44	380.76

Sources: Extracted from the Unit-level Records of Consumer Expenditure Survey, 55th Round of NSS, 1999–2000

Table 6

Per capita annual drugs and other medical expenditure (urban)

(Rs.)

State	Inpatient		Outpatient		Aggregate	
	Drugs	Total	Drugs	Total	Total drugs	OOP
Andhra Pradesh	34.14	84.91	273.94	346.81	308.08	431.72
Assam	55.39	122.74	251.96	325.99	307.35	448.73
Bihar	19.31	30.10	190.20	224.90	209.51	255.00
Delhi	127.95	221.68	306.51	375.97	434.46	597.65
Goa	162.98	280.65	441.53	537.69	604.51	818.34
Gujarat	76.87	152.70	276.92	355.92	353.80	508.62
Haryana	129.17	274.87	482.63	527.21	611.80	802.08
Himachal Pradesh	128.62	159.80	365.97	505.06	494.60	664.86
Jammu and Kashmir	64.54	103.98	294.49	337.48	359.04	441.46
Karnataka	68.36	174.08	229.55	358.29	297.91	532.37
Kerala	142.83	348.62	457.30	588.28	600.13	936.90
Madhya Pradesh	66.59	109.83	323.41	388.81	390.00	498.64
Maharashtra	118.66	246.14	363.23	569.46	481.89	815.60
Orissa	66.51	79.89	276.13	299.70	342.64	379.60
Punjab	56.31	176.58	441.35	496.85	497.66	673.43
Rajasthan	57.80	94.34	380.54	428.23	438.34	522.57
Tamil Nadu	65.29	178.24	280.93	385.28	346.22	563.52
Uttar Pradesh	55.27	92.73	389.11	452.72	444.38	545.45
West Bengal	50.21	128.13	332.13	435.78	382.34	563.91
All India	72.76	153.68	326.27	423.16	399.02	576.83

Sources: Extracted from the Unit-level Records of Consumer Expenditure Survey, 55th Round of NSS, 1999–2000

Table 7

State-wise government drug expenditure in India (2001–02)

State	Drugs	Materials and supplies	Total	(Rs in lakh)	Drug Expenditure as % of Health Expenditure
				Health Expenditure (Rev.)	
Andhra Pradesh	7923.09	4781.45	12704.54	131424.08	9.67
Assam	0.00	1530.10	1530.10	32690.82	4.68
Bihar	1996.90	206.29	2203.19	71348.49	3.09
Chhattisgarh	1822.47	680.22	2502.69	22587.10	11.08
Gujarat	1253.76	1440.06	2693.82	71547.95	3.77
Haryana	N.A.	3096.12	3096.12	31470.98	9.84
Karnataka	6927.17	856.82	7783.99	98633.19	7.89
Kerala	N.A.	12420.68	12420.68	72931.59	17.03
Maharashtra	10.00	20295.91	20305.91	178379.51	11.38
Madhya Pradesh	3965.86	3956.04	7921.90	66689.30	11.88
Orissa	1768.98	361.30	2130.28	42135.78	5.06
Punjab	N.A.	916.32	916.32	61826.45	1.48
Rajasthan	3952.80	5092.25	9045.05	97311.61	9.29
Tamil Nadu	16428.68	1668.57	18097.25	118432.85	15.28
Uttar Pradesh	5938.25	1166.04	7104.29	135578.81	5.24
West Bengal	5005.25	793.23	5798.48	131948.35	4.39
Central Govt.*		72649.23	72649.23	597700.00	12.15
All India*	56993.21	131910.63	188903.84	1962636.86	9.63

Note: Many states report drug expenditure under the category of Materials and supplies. Materials and supplies include hospital accessories, bedding cloth, materials supply, laboratory charges, charges, Others and X-ray materials. Here we have included materials supply only.

* Includes only 16 states total reported in the table, which account for around 85%.

** The drug budget for the Central Government includes expenditure incurred on four National Programmes—Blindness Control Programme, TB Programme, Leprosy Programme and Vector Borne Disease Control Programme.

Source: Budget documents, respective State and Central Government

Table 8**Growth rate of bulk drugs and formulations production in India since the 1970s**

Growth of production	1970s	1980s	1990s	2000-03	1970-2003
Bulk drugs	20.28	10.08	19.49	19.76	12.38
Formulations	16.88	11.07	16.42	14.68	11.05
Total production	17.39	10.91	16.95	15.72	11.17

Note: All values are percentages. Growth rates refer to compound growth rates based on current prices.
Source: Computed on the basis of IDMA, various issues.

This resulted in the invention and introduction of products ensuring high growth and monopoly profits. Radical invention and introduction of new drug technologies stimulated the industry to transform massively. Unprecedented attention to 'wonder drugs' through the magic-bullet technology shifted the focus from treating the symptoms to healing the disease itself. On the domestic front, the government intervened by establishing a few public-owned life-saving and essential drugs-producing companies. The Indian Patents Act, 1970, the FERA (Foreign Exchange Regulation Act), 1973, acted as a boost to the domestic growth of this all-important industry.

Skewed production priorities

Even though drug production witnessed a phenomenal upsurge during the past three decades of the century, the production and sale of products also reflected market potential. [However, the market potential for drugs is largely induced-through marketing, advertising and distributional network.] Thus, drug production mainly catered to those who have enough purchasing power.

Table 9 above exposes skewed production priorities by the drug industry. Irrational, non-essential and hazardous drugs

Table 9**Pattern of pharmaceutical sales in India, 1999**

Product rank	Products	Sales (In crore)	Market share(%)	Market Product description
1	Becosules	79.42	1.39	Irrational vitamin combination
3	Corex	61.27	1.07	Irrational cough mixture
9	Liv-52	62.17	1.09	Useless liver drug
11	Dexorgange	47.40	0.83	Blood tonic
12	Digene	46.69	0.82	Needless antacid
17	Combiflam	43.05	0.75	Irrational analgesic combination
20	Polybion	40.76	0.71	Irrational vitamin combination
21	Glucon-D	39.66	0.69	Useless nutrients
22	Evion	39.19	0.69	Irrational vitamin combination
25	Revital	38.98	0.68	Oral ginseng tonic

Source: Compiled from ORG-Retail Sales Audit, June 1999

have flooded the market. Take for instance, the top twenty-five formulations sold in the Indian market in 1999. Of the top 10 products, two belong to the category of irrational vitamin combination and cough syrup while the other drug is a useless liver drug. Ten of the top 25 products sold in India in 1999 belonged to either one of these categories: blood tonic, cough expectorant, non-drug, analgesics, nutrients, liver drug, etc. which are either hazardous, non-essential or irrational. These ten inessential and irrational drugs together accounted for nearly 10% of the total value of 300 products.

Table 10 clearly sums in part the changing pattern of drug requirements according to the shifting disease profile of India. Lifestyle drug categories such as cardiovascular drugs, hormones, nutraceuticals are growing in magnitude with every passing year. These categories together accounted for over one-fifth of the total pharmaceutical sales in 2002.

Fig 10**Market share of drugs by therapeutic segment (2002)**

Therapeutic Segments	Total retail sales	Percent to total market
Alimentary system	2137	12.50
Cardiovascular system	2182	12.76
Central Nervous system	1157	6.76
Musculoskeletal disorders	1367	7.99
Hormones	2362	13.81
Genitourinary system	738	4.31
Infections and infestations	3726	21.79
Nutraceuticals	463	2.71
Respiratory system	1734	10.14
Eye	273	1.60
Allergic disorders	31	0.18
Skin	911	5.32
Metabolism	21	0.12
Total market	17,102	100.00

Source: Calculated from ORG-Retail Sales Audit, June 1999
Note: The above analysis is based on the leading 300 products reported in the source. The value of these leading products accounts for 46.81% of the total market value.

Expensive pre-digested nutritious supplements such as protein foods, malt tonics, various vitamins, calcium, haemoglobin, iron, etc. form a notable share of the total market sales of drugs.

Similarly, dehydration caused by diarrhoea, particularly in children, also accounts for innumerable prescriptions, although dehydration can be easily treated with the combination of simple household items such as water, salt and sugar or oral rehydration solution (ORS). Similarly, the share of the anti-tuberculosis drug market accounts for a meagre 2%, while a significant burden of disease and death in India is caused by tuberculosis.

In this context, it is interesting to note the contribution made by different players in the market. Table 11 provides an

Table 11

Contribution of essential and inessential drugs by domestic and multinationals firms

(Rs in crore)

Formulations	1985-86			1998-99		
	Top 50 companies	MNCs	Domestic companies	Top 50 companies	MNCs	Domestic companies
Total turnover	1008.7	573.2(56.82)	435.5(43.17)	2113.29	1146.16(54.24)	967.12(45.76)
Turnover of few inessential, irrational drugs	276.2	195.1(70.7)	81.1(29.3)	591.68	511.97(86.53)	79.71(13.47)
Antacid, antitflatuent	30.0	19.2(64.0)	10.8(36.0)	157.50	77.99(49.45)	79.71(50.55)
Vitamins	91.2	76.1(83.4)	15.1(16.6)	260.35	260.35(100)	—
Anti-anaemia preparation	42.0	18.5(44.1)	23.5(55.9)	47.40	47.40(100)	—
Rubs and balms	12.3	12.3(100)	—	32.09	32.09(100)	—
Cough and cold preparations	48.7	37.5(77%)	11.2(23)	94.14	94.14(100)	—
Turnover of few essential drugs	327.8	128.8(39.3)	199(60.7)	690.68	198.34(28.72)	492.34(71.28)
Antibiotics	225.4	81.1(36)	144.3(64)	522.51	129.08(24.70)	393.43(75.30)
Anti-tuberculosis drugs	20.6	4.0(19.4)	16.6(80.6)	38.88	—	38.88(100)
Vaccines	1.5	0.5(33.3)	1.0(66.7)	32.59	32.59(100)	—
Anti-diabetic drugs	10.4	9.4(90.4)	1.0(9.6)	36.67	36.67(100)	—
Antiseptic, anti-infective	21.5	10.8(50.2)	10.7(49.8)	29.14	—	29.14(100)
Antiparasitic (amoebicides)	16.7	5.8(34.7)	10.9(65.3)	30.89	—	30.89(100)

Note: Figures in parentheses denote the percentage share between domestic and multinational corporations. The above figures relate only to the top 50 products analysed among 300 products listed in the source.
Source: Computed from ORG-Retail Sales Audit, March 1986 and June 1999

analysis based on the top 50 products for the period 1985-86 and 1998-99. While examining the leading 50 formulations, only products that fall under the categories mentioned in Table 10 are taken up for consideration here while the rest are excluded from the analysis.

The dominant proportion of transnational corporations in the production and sale of inessential and irrational combinations of drugs is apparent from Table 11 wherein vitamins, rubs and balms, and cold and cough preparations account for 100% in the production in 1998-99, mirroring almost similar trends witnessed in 1985-86. The strength of domestic Indian companies lies in categories such as antibiotics, anti-tuberculosis and antiparasitic, anti-infective and antiseptic preparations. The analysis clearly demonstrates that while multinationals concentrate on high-value, low-volume products, the domestic industry, on the other hand, concentrates on high-volume, low-value products. The former promotes brand names while the latter by generic brands.

Trends in the pharmaceutical trade

The role of the drug trade assumes importance, as India was historically dependent on drug imports when the domestic industry was in a nascent stage. The import of bulk drugs has been considerable and increased during the 1950s and 1960s, as formulations were prepared with basic bulk drugs, mainly by transnational companies. For instance, the import of bulk drugs and formulations registered an upward trend from Rs 13.17 crore in 1963-64 to Rs 37.54 crore in 1973-74. Nevertheless, export marked a sharp and significant increase during this period from a meagre Rs 2 crore to Rs 37.54 crore, thereby helping to reduce the trade gap in the phar-

maceutical industry to a marginal Rs 4 lakh during the period.

But the strength of the Indian pharmaceutical trade lies in the formulations market due to its cost advantage. Compared to bulk drugs, the export of formulations steadily increased from nearly Rs 35 crore in 1980-81 to around Rs 413 crore in 1990-91 to a staggering Rs 3038.5 crore in 1998-99. The export of Indian pharmaceutical products witnessed a quantum jump in the 1990s; the growth rate was 32.85% (Table 12). The export of bulk drug items, however, has been on a very small scale for a long period in the history of the drug

Table 12

Growth of trade in pharmaceuticals in India in the 1980s and 1990s

Growth of pharmaceutical trade	1980s (%)	1990s (%)
Bulk drugs export	50.58	24.20
Formulations export	19.54	30.84
Total pharmaceutical export	30.31	32.85
Bulk drugs import	18.13	27.71
Formulations import	34.54	27.72
Total pharmaceutical import	20.17	32.97

Note: Growth rate indicates the compound growth rate
Source: Worked out from IDMA and OPPI Annual Reports

trade. However, trends in the late 1990s indicate a reversal of this trend. The amount of exports during 1998-99 was estimated at about Rs 2400 crore. Indian domestic pharmaceutical companies have made major inroads into the highly competitive generic segments of the world market. It is this market which is fetching a high value for Indian companies and

steadily building an excellent infrastructure network around the world.

Bulk drug import has been a significant item in the basket of total imports in the 1950s and 1960s. Although the extent of its significance has undergone tremendous change, bulk drug still accounts for one-half to one-third of the total bulk drug consumption. In 1980-81, against the total bulk drug production of Rs 240 crore, import amounted to nearly Rs 90 crore. Further, trade figures reveal that during 1998-99, the total import of bulk drugs was roughly Rs 2000 crore as opposed to the domestic production of around Rs 3200 crore. From Table 11 it is apparent that the total import growth calculated for the 1990s point to a growth rate of around 33%.

Concentration in Indian Drug Industry

A casual observer might assume from Table 13 that the Indian pharmaceutical market is extremely competitive as even the top most firm could not garner more than 7% of the total market share, while the share of the top 10 companies is only around 30% (ICRA 1999). A comparative analysis of Table 13 reveals some interesting insights. Over a span of two decades, the contribution made by the top 10 players have come down from around 40% in 1976 to 30% in 1998. The other point that needs to be noted is that a majority of the leading companies in 1976 (7 out of 10) were multinational drug corporations. A complete reversal of the trend was seen in 1998, wherein 7 out of 10 top companies were domestic ones.

However, a simple analysis of the above pattern is misleading because the market for drugs is not a homogeneous, single-product category but a multiproduct one. Thus, the market for pharmaceuticals can be subgrouped into a large number of independent submarkets (characterized by low

cross-elasticities of demand). This is because the medicines prescribed for cardiovascular disease cannot be administered to a patient suffering from cancer. Consequently, one cannot observe drug manufacturers competing on an industry-wide basis. The following paragraphs would give a fair idea of the concentration in the Indian pharmaceutical market, which is measured by (i) the dominant market share held by a handful of companies, in terms of sales, and (ii) dominance of a small number of products within each therapeutic class.

Table 14 provides information on the market share enjoyed by leading drugs under each therapeutic class. It also shows the market share of drug companies manufacturing top products. Table 14 displays an extreme concentration persisting across therapeutic groups in the Indian drug industry. A detailed analysis by various therapeutic segments of drugs demolishes the claim of the industry lobby that competition prevails in the industry. The number of drugs covered in the ORG-MARG database under all the therapeutic segments for 1998-99 is the top 300 products, which is close to half of the total retail market in India. This is against an estimated 20,000 drugs in the Indian drug market. The table apparently establishes the supremacy of a few companies and correspondingly a handful of its drugs in each therapeutic category. Out of 32 therapeutic classes considered in the analysis, in 19 markets, four and less than four companies retain dominant shares. Their respective market shares range from 30% to more than 90% in a few cases. For instance, the market for streptomycin points to an extreme concentration, wherein just one company commands the entire market (93.27%) while the class of vaccines, rubs and other inhalants, antiseptics and other penicillin markets are held by 3-4 companies, respectively. The share of top products also follows a similar pattern in various therapeutic groups.

Closely followed by these patterns, another 13 therapeutic segments show less extreme concentration. Included in this category are 5-8 companies whose market share in each therapeutic market is in the range of 30%-70%. Another noteworthy pattern that emerges from Table 14 is that the element of oligopoly cuts across the entire spectrum of the therapeutic class, whether it is the case of essential drugs like antibiotics, anti-tuberculosis drugs or inessential drugs such as vitamins, cough and cold preparations, tonics, etc. The drug industry is extremely concentrated, debunking the theory that the drug market in India is competitive.

Price, procurement and regulation of essential drugs

Drug price control in other countries

Worldwide, drug prices are subject to controls and regulations. A host of policy instruments are exercised to rein drug prices from increasing to unreasonable levels. Such controls take the following forms, either singly or in combination with more than one instrument: cap on mark-ups, fixed margins to wholesalers/pharmacists, price freezes, reimbursements, reference pricing, contributions to insurance pre-

Table 13

Retail market share of top 10 pharmaceutical companies in India

Company	Market share 1976 (%)	Company	Market share 1998 (%)
Sarabhai	7.1	Glaxo-Wellcome	6.7
Glaxo	6.2	Cipla	4.2
Pfizer	5.9	Ranbaxy	3.5
Alembic	4.2	Hoechst-Marrion-Roussel	3.2
Hoechst	3.6	Torrent pharmaceuticals	2.4
Lederle	2.5	Alembic	2.4
Parke Davis	2.3	Wockhardt-Merind	2.3
Abbott	2.3	Lupin Labs	2.3
Ciba-Geigy	2.3	Knoll pharmaceuticals	2.3
Sandoz	2.2	Pfizer	2.3
Total for above companies	39.6	Total for above companies	31.6

Source: Figures for 1976 are adapted from Singh (1985), while those for 1998 have been compiled from PROWESS Database, Centre for Monitoring Indian Economy (CMIE), Mumbai, 2000

Table 14

Concentration in the Indian drug industry

Therapeutic group	Leading products		Number of products	Number of companies
	Amount of sales (Rs in crore)	%		
Chloramphenicol*	20.84	43.41	1	1
Streptomycin*	14.06	93.27	1	1
Mineral supplements	49.15	39.00	2	2
Tonics	25.76	31.00	2	2
Laxatives	22.81	32.00	2	2
Anticoagulants	21.61	32.43	2	1
All other antibiotics*	39.22	35.62	2	2
Vaccines	66.96	74.65	3	3
Trimethoprim combinations*	65.74	65.31	3	3
Systemic corticosteroids	122.77	71.00	4	4
Antiepileptics	64.05	44.27	4	4
Rubs, other inhalants	100.19	83.41	4	4
Antidiabetic drugs	108.78	38.34	4	4
Antispasmodics, etc.	51.18	41.30	4	4
Antiseptics, disinfectants	71.47	78.63	4	4
Other penicillins*	52.97	86.53	4	3
Sex hormones	73.71	31.23	5	4
Topical corticosteroids	115.22	42.00	6	5
Cough preparations	73.05	41.23	6	6
Tuberculostatics	153.58	44.69	6	4
Tetracyclines and combinations*	79.69	57.73	6	6
Hypotensives	92.56	36.84	7	7
Antiasthmatics	119.61	45.88	7	4
Vitamins	296.91	38.87	8	6
Cardiac therapy	135.96	31.64	8	8
Cold preparations	197.30	41.65	8	8
Antacid, antiflatulents, etc.	158.05	55.71	8	5
Anti-inflammatory, anti-rheumatics	255.04	41.09	8	8
Analgesics	150.17	51.28	8	8
Ampicillin/amoxycillin*	250.37	38.92	8	8
Cephalosporins*	297.41	43.3	8	5
Macrolides and similar preparations*	179.10	69.37	8	6

* broad antibiotics category
Note: Percentages indicate the value of leading products to total sales in each therapeutic group.
Source: Calculated from ORG – Retail Sales Audit, June 1999

mium, patient copayments, generic substitution, ceiling on promotional expenditure, differential value added tax on drugs, etc.

Governments in various countries undertake cost studies to determine drug prices. While criteria vary from one country to another, countries largely follow comparable methods of pricing between a new product and that of an existing product in a similar therapeutic class. For new 'breakthrough' products, prices are worked out based on therapeutic merit. France, Canada, Egypt, Mexico follow this pattern of price fixation.

Most countries have some form of reimbursement mechanism to purchase drugs for the benefit of patients. France regulates margins allowed for wholesalers and pharmacists of

reimbursable drugs. In fact, in France, 91% of medicines sold by retail drug stores are on the reimbursable list. All reimbursable drugs in Italy are price controlled. Reimbursed generic prices are allowed to be sold 20% below the original price. In Italy the prices of prescription drug that are reimbursed cannot exceed the 'European average' price. In case the reimbursed price of a drug exceeds the European average, the product under question will automatically be removed from the reimbursement list. However, non-reimbursable drug prices can be changed once a year.

Reimbursement drug prices are controlled by a reference pricing system in Germany, although prescription drug prices are allowed to be changed freely. Reference pricing is one in which drugs that are therapeutically equivalent fall into one class and are reimbursed at similar levels. The difference that arises between the reference and market price is to be paid by patients. All prescription drugs in Japan are effectively on the reimbursement list. Reimbursement drug prices are subject to price control based on the average level of prices of similar categories. Britain allows for reimbursement on all drugs unless they are on the negative list. Although newly introduced prescription drugs ones are not controlled at the launch of the new product, generic prices are subject to controls.

Interestingly, Spain controls even the launch price of prescription drugs. The criteria for price control are based on cost of production, profit allowance and anticipated volume of sales. One of the highlights of the health care scheme in Spain and Switzerland is that a strict monitoring of the doctor's prescribing behaviour is undertaken and those who are found to indulge in high prescribing are warned by the government. Switzerland allows manufacturers to freely fix prescription drug prices, which are not on the reimbursable list. On the other hand, the reimbursable generic drug price is set at below 25% of the original.

Over-the-counter (OTC) prices are generally free of price control in most countries. Although drug prices are largely control-free in the US, the government fixes a specified discount on the market prices of those drugs that are sold to Medicaid programmes. Reimbursement of drug prices in the US varies, since pharmacies have different agreements with various insurance companies.

Fixing margins on the profit of pharmaceutical companies also forms part of drug price control/management. Egypt sets a maximum limit of 20% and 12% on profit to manufacturers of locally produced drugs and imported drugs, respectively. The respective profit margins for wholesalers and retailers are 7% and 20%. While manufacturers are allowed a margin of 7%–10% in Mexico, wholesalers can retain up to 18.5%. Pharmacists in Mexico are provided two options of margins–

Box 4**Drug Price: Headed northwards?**

- Analyses show that 11 out of 15 antibiotic drugs witnessed a price rise in the range of 1%-15% annually during 1994-2004.
 - Anti-TB drugs-Eight out of 10 drugs had shown price increases ranging between 2% and 13% per annum.
 - General rise in the prices of drugs across all sub-therapeutic categories of cardiovascular diseases: cardiac disorders-2%-16%; anti-anginals-5%-6%; peripheral vasodilators and antihypertensives-1%-7% annually.
 - Vaccines and antitoxins registered a meagre price rise during the period.
 - Antimalarial drugs registered mixed price trends and similar conditions prevailed among cancer drugs.
- A price declining trend was observed among HIV/AIDS drugs

one for drugs launched before 1975 and those post-1975. Margin ceilings also exist in Spain with wholesalers availing 12.4% and pharmacies getting 43.5% of manufacturers' retail price. Switzerland allows wholesalers to avail of a margin in the range of 11.1% to 17%, depending on the drug price. Margins allowed for pharmacies are in the range of 26% to 70%. The margin allowed for wholesalers by the manufacturer is only around 2% and for pharmacies it is about 15% in the US.

Drug prices in many countries are linked to a ceiling on promotional spending by pharmaceutical firms. France levies an impost ranging between 9% and 20% on the proportion of promotional expenditure to sales of drug companies. Britain restricts promotional spending to a percentage of drug sales to the National Health Service. Spain places a ceiling on the promotional expenditure for a drug at 12%-14% of the producers' sale price.

The health care system in developed market economies has evolved in such a way that patients need not bear the entire amount OOP. The system is funded mainly by employee/employer contributions towards insurance payments and patient copayments. France has a system in which even copayments are borne either by private or by non-profit insurance plans. In Italy, however, patients are required to pay 50% of the price, depending on the category of drug. While half of Spain's universal coverage of health care essentially comes from taxation, the rest is contributed by social security schemes, copayments and other OOP payments.

Price control/management becomes cumbersome and impossible when the number of formulations is very large. Egypt successfully manages this impossible scenario by approving only 4000 medicines. In fact, the number of manufacturers producing a drug is restricted to four or five. For a new entrant beyond this level, the new firm is permitted to sell the drug 30% below the average price of the drug sold in the market. Similarly, to ensure the rational use of drugs, Mexico encourages single-ingredient formulations.

Prescription drugs attract a value added tax (VAT) of only

6% while OTC drugs are imposed a tax of 17.5% in the Netherlands. Switzerland imposes only 2% VAT on drugs. In Indonesia, VAT is fixed at 10% of manufacturers' selling price except on drugs that are on the essential drugs list (GOI 1999).

The drug price control system in India

In the post-independence period, statutory control on drugs was first introduced in 1962. However, owing to criticism from the industry, the Government made changes in the Drug Price Control Order. Subsequently, the Government identified a list of 18 essential drugs and referred them to the Tariff Commission. The Tariff Commission was asked to go into the various aspects of the cost structure of these essential life-saving drugs and asked it to recommend reasonable prices. Realizing the importance of checking the prices of drugs from escalating to phenomenal heights, the Drug Price Control Order, the first of its kind with a thorough analysis, was introduced by the Government of India in 1970. The Price Control Order was meant to keep the prices of drugs at affordable limits to the consumers and at the same time ensure that producers received reasonable returns. The Order captured 347 bulk drugs under its net, which were placed in various categories. The minimum percentage of profit margin was granted to different categories and producers were allowed to charge a maximum amount of post-manufacturing expenses. The other vital feature of this Order relates to the stipulation of minimum ratio of bulk drugs to formulations.

Objectives of drug price control

A broad-based drug policy was formulated based on Hathi Committee Report of 1975. Based on Hathi Committee's recommendations, the Government announced Drug (Price Control) Policy, 1979. Some of the key objectives of the Policy were:

- to ensure adequate availability of drugs
- to provide drugs at affordable prices
- to ensure the quality of drugs and check medicines from being adulterated
- to achieve self-sufficiency in production and self-reliance in drug technology.

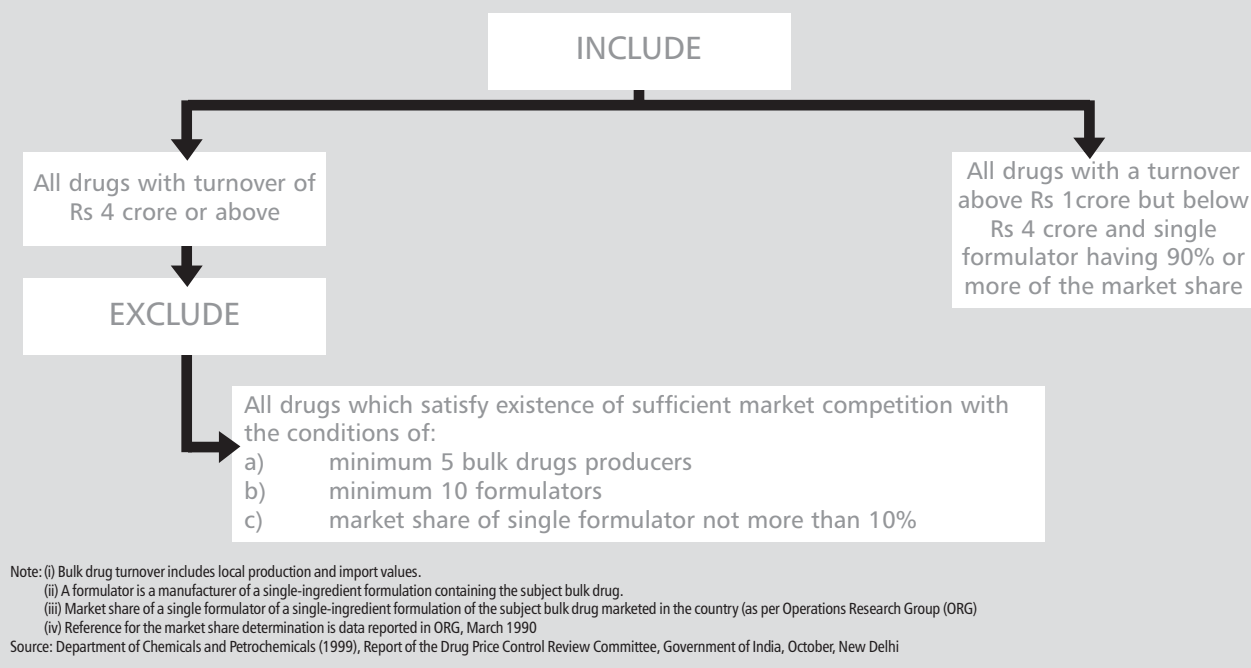
Rationale for drug price control

The drug market is unique. Besides market failure, the overall health condition in India has made it all the more necessary to have a stricter price control regime. Detailed discussion of these follows:

- The demand for medicines is uncertain and consequently becomes inevitable. A patient with a potential disease cannot afford to ignore taking medicines as the disease may turn out to be fatal or result in permanent disability,
- In view of the above, it becomes pertinent on the part of the patients to buy medicines as advised by their doctors irrespective of the price. Demand inelasticity of consumers thus provides added advantage to drug firms to charge a rent-seeking price and, moreover, the pre-condition of con-

Fig 2

Criteria for inclusion of drugs under price control, DPCO, 1995



- The market for formulations, particularly if one goes by various therapeutic categories, is either monopoly or oligopoly. Price competition does not exist.

The above market imperfections apart, with nearly one-third of the Indian population below poverty line, health conditions make it pertinent to allow for price control.

Over the years, however, the controls are being dismantled gradually and the number of bulk drugs that were under price control has been brought down gradually to a minimum level. In 1979, 347 bulk drugs were under the Price Control Order, which came down to 142 in 1987. Drastically pruning the list further, the Drug Price Control Order of 1995 sought to limit the control list to just 76 drugs. Along with gradual reduction in the number of drugs under price control, certain procedures were greatly simplified and coverage of price-controlled drugs underwent enormous changes over the years. Table 15 shows that the number of categories of bulk drugs was pruned from three in 1979 to just one in 1995. With a reduction in the number of categories, the percentage of maximum allowable post-manufacturing expenses (MAPE) were unified to 100% in 1995 against 40%, 55% and 100% in 1979.

As the process of globalization and liberalization are intensifying in India, controls and regulations on a lifeline industry such as the pharmaceutical industry is being lifted. The Drug Price Control Order of 1995 does away with many controls and regulations. The purview of price control was limited to just 76 drugs in 1995. The DPCO delineates certain benchmarks on which price control will be based. These are (i) sales turnover, (ii) market monopoly, and (iii) market competition. Across the board, the price control order fixed 100%

maximum allowable post-manufacturing expenses (MAPE) to all drugs. MAPE refers to the mark-up on the ex-factory costs provided to cover all selling and distribution costs, including the retail and wholesale trade margins.

Impact of price control on drugs and pharmaceuticals

In India, prices of drugs were once considered to among the highest in the world. This trend of high prices has tended to reverse since the 1970s in the wake of a series of policy measures.

The Drug Price Control Order of 1970 brought all drug formulations in two categories: essential and non-essential. While those in the essential category were allowed a mark-up of only 75% in view of their importance, the latter category was allowed 150%. Later, in the 1978 Drug Policy, a slight modification was made by classifying formulations into four categories. The four categories and their respective mark-ups are as follows: (i) Category I attracted only 40% mark-up; (ii) Category II was allowed 55% mark-up; (iii) Category III was permitted to charge 100% mark-up; and (iv) Category IV was totally exempt from price control.

One of the earliest price analyses at the disaggregated level was done by Rane (1990) while attempting to assess the impact of the DPCO, 1987. The study was essentially carried out a simple relative comparison of drug prices between two periods—1986 representing the pre-policy period and 1990 denoting the post-price policy regime—as lack of adequate data on weights forced him to settle for this method. The price increase between these periods as a result of price policy category-wise show that most of them were in double digits in the

period following price decontrol. The highest rise was registered in the case of skin preparations, accounting for nearly 50% followed by respiratory system preparations recording a 32% price increase. The lowest increase was registered in the case of musculoskeletal preparations with 9.96%. Therefore, such a disaggregated assessment of increase in drug prices uncovers many facts which are not captured in the wholesale drug price index.

Analysis of the impact of the DPCO, 1995

This section comprehensively probes into the impact of the DPCO, 1995 on drug prices. A comparative analysis of pre- and post-DPCO, 1995 price trends of major essential drugs is considered. The analysis basically involves examining price trends of essential drugs that are part of the DPCO, 1995 and those that are outside price control.

Methodology for the analysis

The basis for delineating drugs under price control and decontrol are derived from the government list of drugs under control (GOI 1995). Further, from this list only essential drugs were considered. Price data for the analysis are basically culled out from various December (except 2004, where the issue of August has been obtained) issues of the Monthly Index of Medical Specialities (MIMS), India spanning 11 years from 1994 to 2004.

The number of essential drugs considered for analysis is as follows: (i) a total of 152 formulation packs relating to 14 disease conditions from the Essential Drugs List were taken into account. These 152 formulation packs were of similar strength and numbers (dosages). Out of 152 medicines, a total 115 medicines, constituting around 75% of the total medicines were decontrolled drugs while the rest 37 are price-controlled

Table 15

Comparative chart summarizing various drug price control orders

Items under DPCOs	DPCO 1979	DPCO 1987	DPCO 1995
Number of drugs under price control	347	142	76
Number of categories under which the above drugs were categorized	3	2	1
MAPE allowed on normative/national ex-factory costs to meet post-manufacturing expenses and to provide for margin to the manufacturers (5)			
Category I	40	75	100
Category II	55	100	NA
Category III	100	NA	NA
Category IV	60	NA	NA
Percentage of total domestic pharmaceutical sales covered under price control (approximately)	90	70	50

MAPE: maximum allowable post-manufacturing expenses
Source: Indian Drug Manufacturers Association (IDMA) Bulletin 1998;XXIX:202

Box 5

Exorbitant profit and trade margins: Is monopoly purchase the answer?

- The initial drug price is set high.
- The distribution network is extremely complex.
- Trade margins range from 100% to a whopping 5600%.
- The highest and lowest price differences between market and tender prices in the case of cancer drugs were about 275% and 1166%, respectively.
- A huge price difference is observed among maternal and mental health conditions.
- Maternal health drugs are 117% and 4028% for the lowest- and highest-priced drug category.
- Mental health drugs are 329% and 5102% for lowest- and highest-priced drug category.
- Monopsony can save up huge cost.
- Fixing trade margins is another solution.

drugs, accounting for 25%. Subsequently, the retail price of the formulations of each of these drugs was obtained from MIMS India. Although the number of products considered initially was 600 plus, after elimination the number came down to 152 products. Then we arrived at the annual price change (in percentage terms) of formulations under each drug.

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) products that are not listed in MIMS India continuously for 11 years are also ignored from the analysis.

The price change during the period from 1994 to 2004 is captured by working out the year-on-year percentage change and cumulative 11-year price change. The observed price change-annual percentage price change-is given in Tables 16 and 17.

The observed price change among 12 formulations packs accounting for around 8% of total formulation witnessed more than 10% price rise annually during 1994-2004. Another 38 medicines, accounting for 25% of the total formulations considered, showed price increases in the range of 5%-9% during the same period. A moderate price rise of less than 5% was registered among 56 formulations packs, which accounts for 37% of the total packs considered. Among them, 19 formulations are under the DPCO, 1995. Virtually no price change was recorded among another 19 formulations during this period, constituting around 12% of the packs. Such price rises was observed across all therapeutic categories.

A general trend that emerges from Tables 15 and 16 clearly point out that over one-fifth of the 36 price-controlled drugs under consideration have tended to be either stable or have shown a

Table 16

Price change in drugs used for the treatment of cardiovascular diseases

Drug name	Formulation	Therapeutic group	% Price change (1994 to 2004)
Bisoprolol	Concor	Anti-anginals\	-5.55
Carboprost	Prostodin	Haemostatics	-2.74
Atenolol	Tenofed	Peripheral Vasodilators	-0.35
Metoprolol	Selopres	Anti-Hypertensives	0.00
Hydrochlorothiazide	Arkamin-H	Anti-Hypertensives	2.05
Ramipril	Cardace	Cardiac Disorders	2.13
Dopamine	Dopinga	Cardiac Disorders	3.49
Nifedipine	Cardules Plus	Anti-anginals	3.74
Enalapril maleate	En.Ace.	Anti-Hypertensives	4.52
Indapamide	Natrilix SR	Anti-hypotensives	5.87
Enalapril maleate	Enace-D	Anti-Hypertensives	5.87
Nifedipine	Depin	Anti-anginals	6.24
Indapamide	Lorvas	Anti-hypotensives	6.78
Hydrochlorothiazide	Adelphane-Esidrex	Anti-Hypertensives	7.00
Atenolol	Tenolol	Peripheral Vasodilators	7.51
Digoxin	Cardioxin	Cardiac Disorders	11.28
Digoxin	Lanoxin	Cardiac Disorders	16.64

Source : Calculated from MIMS India, 1994 to 2004

Price change in drugs used for the treatment of central nervous system disorders

Drug name	Formulation	Therapeutic group	% Price change (1994 to 2004)
Carbamazepine	Mazetol	Analgesics and Antipyretics	-1.36
Lithium Carbonate	Licab/XL	Antidepressants	-1.04
Lorazepam	Larpose	Sedatives and Tranquillisers	-0.42
Paracetamol	Disprin Paracetamol	Analgesics and Antipyretics	-0.26
Trihexyphenidyl	Trincalm Forte/Plus	Sedatives and Tranquillisers	-0.13
Clozapine	Sizopin	Sedatives and Tranquillisers	0.00
Haloperidol	Serenace	Sedatives and Tranquillisers	0.00
Phenobarbitone	Gardenal	Anticonvulsants	0.00
Phenytoin Sodium	Dilantin	Anticonvulsants	0.00
Clozapine	Lozapin	Sedatives and Tranquillisers	1.76
Imipramine	Antidep	Antidepressants	2.12
Diazepam	Paxum	Sedatives and Tranquillisers	2.40
Metoclopramide	Reglan	Antiemetics and Antinauseants	3.57
Diazepam	Elcion CR	Sedatives and Tranquillisers	4.13
Diphenyl Hydantoin	Epsolin	Anticonvulsants	4.21
Fluoxetine	Fludac	Antidepressants	5.35
Lorazepam	Ativan	Sedatives and Tranquillisers	5.66
Sodium Valproate	Epilax	Anticonvulsants	5.83
Trihexyphenidyl	Pacitane	Neurodegenerative Disease	6.70
Phenobarbitone	Garoin	Anticonvulsants	7.00
Paracetamol	Zimalgin	Hypnotics	7.48
Phenytoin Sodium	Eptoin	Anticonvulsants	8.32
Fluphenazine	Anatensol Inj.	Sedatives and Tranquillisers	12.99

Source : Calculated from MIMS India, 1994 to 2004

Table 16

Price Change in Drugs of Infections and infestations

Drug name	Formulation	Price control	Therapeutic group	% Price change (1994 to 2004)
Ceftriaxone	Monocef I.V.	DPCO 95	Antibiotics	-2.58
Ceftriaxone	Oframax	DPCO 95	Antibiotics	-0.17
Penicillin	Pentids	DPCO 95	Antibiotics	-0.05
Chloramphenicol	Reclor	Decontrolled Drugs	Antibiotics	0.00
Ciprofloxacin	Ciprowin	DPCO 95	Sulphonamides and other Bact.	0.00
Penicillin	Pencom	DPCO 95	Antibiotics	0.58
Cefotaxime	Claforan	DPCO 95	Antibiotics	2.22
Metronidazole	Flagyl	DPCO 95	Anti-amoebics, anti-giardiasis	2.52
Erythromycin	Eltocin	DPCO 95	Antibiotics	3.03
Ciprofloxacin	Ciplox	DPCO 95	Sulphonamides and other Bact.	3.38
Cloxacillin	Supremox Inj.	DPCO 95	Antibiotics	3.89
Metronidazole	Aristogyl	DPCO 95	Anti-amoebics, anti-giardiasis	4.74
Chloramphenicol	Chloromycetin	Decontrolled Drugs	Antibiotics	5.73
Amoxicillin	Novaclox	Decontrolled Drugs	Antibiotics	7.19
Erythromycin	Erythocin	DPCO 95	Antibiotics	8.57
Amoxicillin	Novomox	Decontrolled Drugs	Antibiotics	8.67
Ampicillin	Campicilin	Decontrolled Drugs	Antibiotics	10.90
Cloxacillin	Amplus	DPCO 95	Antibiotics	12.29
Ampicillin	Ampipen	Decontrolled Drugs	Antibiotics	15.22
Zidovudine	Retrovir	Decontrolled Drugs	Antivirals	-8.40
Zidovudine	Zidovir	Decontrolled Drugs	Antivirals	-7.67
Chloroquine	Melubrin	DPCO 95	Antimalarials	-2.58
Isoniazid	Myconex 600	Decontrolled Drugs	Antituberculosis	0.00
Pyrazinamide	P-Zide	Decontrolled Drugs	Antituberculosis	0.00
Primaquine	PMQ-INGA	Decontrolled Drugs	Antimalarials	0.00
Mebendazole	Mebex	Decontrolled Drugs	Anthelmintics and other anti-infestive drugs	0.00
Tetanus Toxoid	Dual Antigen	Decontrolled Drugs	Vaccines and anti-toxins	0.30
Tetanus Toxoid	Tripvac	Decontrolled Drugs	Vaccines and anti-toxins	0.72
Mebendazole	Wormin	Decontrolled Drugs	Antivirals	1.62
Streptomycin	Strepto-Erbazide	DPCO 95	Anti-T.B.	2.41
Rifampicin	Rimactane	DPCO 95	Anti-T.B.	2.90
Rifampicin	Rifacilin	DPCO 95	Anti-T.B.	4.97
Chloroquine	Emquin	DPCO 95	Anti-malarials	7.29
Amphotericin B	Fungizone Intravenous	Decontrolled Drugs	Antifungals	7.50
Pyrazinamide	PZA-Ciba	Decontrolled Drugs	Anti-T.B.	7.56
Clofazimine	Hansepran	Decontrolled Drugs	Antileprotics	7.85
Streptomycin	Ambistryn-S	DPCO 95	Anti-T.B.	8.96
Ethambutol	Inambutol Forte	Decontrolled Drugs	Anti-T.B.	9.96
Isoniazid	Rimpazid 450	Decontrolled Drugs	Anti-T.B.	12.39
Ethambutol	Combunex	Decontrolled Drugs	Anti-T.B.	13.45

Source : Calculated from MIMS India, 1994 to 2004

Table 17

Price change in drugs of Alimentary, Musculo-Skeletal Disorders, Hormones and Genito-Urinary System

Drug name	Formulation	Price control	Therapeutic group	% Price change (1994 to 2004)
Prednisolone	Wysolone	DPCO 95	Corticosteroids and related drugs	-5.10
Frusemide	Frusenex	DPCO 95	Diuretics and Antidiuretics	-1.03
Nalidixic Acid	Gramoneg	DPCO 95	Antidiarrhoeals	-0.41
Nalidixic Acid	Negadix	DPCO 95	Urinary anti-infectives	-0.38
Oxytocin	Pitocin	Decontrolled Drugs	Drugs acting on uterus	0.77
Insulin NPH	Lentrad	DPCO 95	Throid and antithroid drugs	1.24
Magnesium Sulphate	Pepticaine	Decontrolled Drugs	Gastro-intestinal sedatives and Ulcer drugs	3.44
Insulin NPH	Actrapid	DPCO 95	Hyper and hypoglycaemics	3.99
Spironolactone	Aldactone	DPCO 95	Diuretics and Antidiuretics	4.34
Ibuprofen	Brufen	DPCO 95	Non-Steroid anti-inlm. Drugs	4.66
Glibenclamide	Daonil	Decontrolled Drugs	Hyper and hypoglycaemics	6.81
Ibuprofen	Combiflam	DPCO 95	Non-Steroid anti-inlm. Drugs	7.16
Frusemide	Frumil	DPCO 95	Diuretics and Antidiuretics	8.24
Glibenclamide	Euglucon	Decontrolled Drugs	Hyper and hypoglycaemics	8.35
Magnesium Sulphate	Solacid	Decontrolled Drugs	Gastro-intestinal sedatives and Ulcer drugs	10.60
Beclomethasone	Anovate	Decontrolled Drugs	Drugs Acting on th ecolon and Rectum	16.37

Source : Calculated from MIMS India, 1994 to 2004

Price change in drugs of Nutrition and Respiratory System

Drug name	Formulation	Price control	Therapeutic group	% Price change (1994 to 2004)
Iron (Salts/complex)	Ferradol	Decontrolled Drugs	Tonics; appetite stimulants	-2.06
Salmeterol	Salmeter	Decontrolled Drugs	Bronchospasm	-0.67
Theophylline	Asmapax Depot	DPCO 95	Bronchospasm	-0.34
Chlorpheniramine	Corex	Decontrolled Drugs	Expectorants, cough suppressants, mucolytics and decongestants	-0.24
Dextrose	Electrobion	Decontrolled Drugs	Mineral and parenteral nutritional suppl.	-0.13
Dextrose	Leclyte	Decontrolled Drugs	Mineral and parenteral nutritional suppl.	0.00
Vitamin A	Rovigon	DPCO 95	Vitamins	0.44
Folic Acid	Astymine Forte	Decontrolled Drugs	Tonics; appetite stimulants	2.05
Salbutamol	Salbetol	DPCO 95	Bronchospasm relaxants	2.57
Calcium Carbonate	Filibon	Decontrolled Drugs	Mineral and parenteral nutritional suppl.	2.90
Salmeterol	Serobid	Decontrolled Drugs	Bronchospasm	3.40
Salbutamol	Salmaplone	DPCO 95	Bronchospasm relaxants	4.06
Iron (Salts/complex)	Imferon	Decontrolled Drugs	Anaemia; Neutropenia	4.36
Terbutaline	Grilinctus-BM	Decontrolled Drugs	Expectorants, Cough Suppr., Decongestants	4.67
Chlorpheniramine	Piriton Expectorant	Decontrolled Drugs	Expectorants, cough suppressants, mucolytics and decongestants	5.42
Vitamin A	Ossivite	DPCO 95	Mineral and parenteral nutritional suppl.	5.62
Terbutaline	Bro-Zedex	Decontrolled Drugs	Expectorants, Cough Suppr., Decongestants	5.69
Theophylline	Alergin	DPCO 95	Bronchospasm	7.36
Budesonide	Pulmicort	Decontrolled Drugs	Bronchospasm relaxants	8.93
Calcium Carbonate	Anemidox	Decontrolled Drugs	Anaemia; Neutropenia	14.18

Source: Calculated from MIMS India, 1994 to 2004

Table 17

Price change in drugs on ENT, Skin and Surgicals

Drug name	Formulation	Price control	Therapeutic group	% Price change (1994 to 2004)
Ketamine	Ketmin Inj.	Decontrolled Drugs	Anaesthetics	-3.58
Hydrocortisone	Furacin-S	Decontrolled Drugs	Topical steroid pre..	0.00
Ketamine	Ketalar	Decontrolled Drugs	Anaesthetics	0.00
Hydrocortisone	Crotorax-HC	Decontrolled Drugs	Topical steroid pre..	0.18
Atropine Sulphate	Bellpino-Atrin	Decontrolled Drugs	Mydriatics and Cycloplegics	1.08
Fluticasone	Zoflut	Decontrolled Drugs	Topical steroid Preps	1.22
Lignocaine	Kemicetine Otological	Decontrolled Drugs	Anti-infective prep.	1.27
Beclomethasone	Beclate/N/C	Decontrolled Drugs	Local reactants on the nose	1.97
Atropine Sulphate	Atrisolon	Decontrolled Drugs	Anti-inflammatory and anti-allergic prep.	2.31
Bupivaccine HCl	Marcaine	Decontrolled Drugs	Surgical antibacterials	2.38
Gentamycin	Genticyn	DPCO 95	Anti-infective prep.	3.26
Silver Sulphadiazine	SSZ Aplicaps	Decontrolled Drugs	Anti-infective prep.	3.56
Gentamycin	Andregen	DPCO 95	Anti-infective prep.	4.19
Adrenaline	Xylocaine C Adrenaline	Decontrolled Drugs	Anaesthetics	6.44
Lignocaine	Otek-AC	Decontrolled Drugs	Anti-infective prep.	7.88
Bupivaccine HCl	Sensorcaine	Decontrolled Drugs	Surgical antibacterials	8.44
Heparin	Beparine/Beparine Cream	Decontrolled Drugs	Misc. skin prep.	8.45
Adrenaline	Gesicain C Adrenaline	Decontrolled Drugs	Anaesthetics	9.99
Meglumine Antimonate	Urografin	Decontrolled Drugs	Diagnostic Agents	18.19

Source : Calculated from MIMS India, 1994 to 2004

Price change in drugs of Cancer and Other Related treatments

Drug name	Formulation	Price control	Therapeutic group	% Price change (1994 to 2004)
Paclitaxel	Intaxel	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	-5.06
Etoposide	Etosid	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	-0.91
Fluorouracil	Fivefluro	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	0.00
Methotrexate	Neotrexate	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	0.00
Tamoxifen	Mamofen	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	0.00
Vincristine	Neocristin	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	0.00
Heparin	Thrombophob	Decontrolled Drugs	Carcino-chemo-therapeutic drugs	0.00
Cisplatin	Kemoplat	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	0.32
Fluorouracil	Fluracil	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	0.71
Bleomycin	Bleocin	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	0.85
Methotrexate	Biotrexate	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	1.04
Vincristine	Cytocristin	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	1.08
Doxorubicin	Doxorubicin-Meiji	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	1.10
Tamoxifen	Nolvadex	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	2.84
Cyclophosphamide	Endoxan-N	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	3.64
Allopurinol	Zyloric	Decontrolled Drugs	Gout	4.80
Chlorambucil	Leukeran	Decontrolled Drugs	Carcino-chemotherapeutic Drugs	8.87

Source : Calculated from MIMS India, 1994 to 2004

downward movement. These drugs are mostly in the category of antibiotics and belong mainly to the class of infections and infestations. Nearly 50% of controlled drugs have shown a moderate 1%–4% increase in price over the past 11 years (1994–2004), across all therapeutic categories. Eight out of 36 price-controlled drugs have witnessed over 5% rise in price; these belong to the category of infections and infestations, bronchospasm, diuretics, etc.

The change in prices has been uneven across therapeutic categories. For instance, out of the 15 packs in the antibiotics category, 11 of them registered a price increase of between 1% and 15% per annum, while the other four medicines witnessed either stable prices or a decline over the 11-year period. In the case of anti-TB drugs, eight out of ten drugs had shown a price rise ranging between 2% to 13% annually during 1994–2004. Among antimalarial drugs, one of them had shown an increase while the remaining two had registered either a stable price or a price decline. In the class of central nervous system drugs, anticonvulsants recorded an increase in price of 0%–8% annually, while antidepressants witnessed no price change in a few categories and others showed a price increase of around 5% per annum.

Anti-HIV drugs show a general price decline. Vaccines and antitoxins registered a meagre rise of less than 1% during this period. One can generally expect this trend as the vaccines market is mostly controlled by the Government and many vaccines have been introduced a long time ago and hence their price cannot be high. Anti-diarrhoeals have also tended to show a price decline during this period.

In the class of cardiovascular drugs, there appears to have been a general rise across all therapeutic segments. Drugs for cardiac disorders registered a price rise in the range of 2%–16% annually. The observed price rise per annum in the category of anti-anginals was in the range of 5%–6%. Peripheral vasodilators and antihypertensives witnessed a price rise in the range of 1%–7%. Anti-cancer drugs have remained stable, except one drug under consideration, which had shown more than 8% price increase annually.

Drug price and retail margins

The analysis above reveals that the drug price rise has displayed an enormous upswing during the past decade despite price controls. The year-on-year annual average price increase for certain categories of drugs has been more than 10%. However, it must be noted that the initial price *per se* is fixed with enormous margins. Trade margins are among the highest in the pharmaceutical industry. The extra sales taxes are levied by respective State Governments, as drugs come under the State-level taxes. Local sales taxes differ from one State to another. Recently, efforts are under way by the Department of Chemicals and Fertilizers to bring the sales taxes of different States under a uniform rate (4%).

The exorbitant trade margins in the pharmaceutical market have become evident recently from the tender purchase

of drugs by Tamil Nadu Medical Services Corporation (TNMSC). Monopoly price can be challenged by monopsony purchase. Tender purchase of drugs by the TNMSC has revealed post-manufacturing margins running into four digits in retail purchase while in tender purchase the prices were at rock bottom (Srinivasan 1999).

The following analysis gives an idea of the exorbitant trade margins and sky-high profits in the drug industry. A simple comparison of formulation packs of comparable size and strength between the market price and tender price is considered here. Therapeutic drugs are basically drawn from the Essential Drugs List. The market price of formulations has been obtained from August issue of MIMS India, 2004 while the tender price has been downloaded from the TNMSC website, applicable during the year 2004. Although nearly 80 formulation packs were considered earlier, only 30 of them have been analysed here. Therefore, two formulations for each of 15 disease conditions (from the Essential Drugs List) were taken into account – the one with the highest price difference and the one with the lowest.

As can be seen from Table 18, price differences ranged from around 100% to 5600%. No systematic pattern in price difference could be deciphered across various health conditions. The highest and lowest price difference in the case of cancer drugs were 275% and 1166%, respectively. The observed price difference of drugs on maternal health are 117% and 4028%, respectively, for the lowest and highest drug category. In the case of mental health, the respective difference is 329% and 5102%.

What has been noted above is only the price difference observed among one single pack (tablets/capsules). If one were to convert this price difference and apply it to the entire retail drug market sales, the resulting trade margins/profit would be mind-boggling. Drug companies are not welfare societies and hence one can assume that a normal profit margin has been included in the quoted tender price. The present-day drug industry is characterized by a complex distribution chain. Therefore, a multipronged strategy needs to be devised to smash this network. A ceiling on trade margins is the need of the hour. The monopoly power of drug companies can also be challenged by monopsony purchase, as the TNMSC procurement as shown. For the Essential Health Intervention package, the necessary drugs could be procured directly from the drug companies by a tender purchase for the entire country. Involving 33 States and Union Territories would only weaken the monopsony power. States could be persuaded to adopt a centralized procurement mode.

Public procurement of essential drugs*

The Central and State Governments spent approximately Rs 2000 crore during 2001–02 on procuring drugs. Apart from this, a few international organizations provide funds (or in kind) for drugs either through the central Government or directly to the States for specific programmes such as leprosy

* This section is largely derived from Parameshwar, (2004). "Drug procurement systems in India", paper submitted to National Commission on Macroeconomics and Health, December.

Table 18

Drug price difference between retail market and tender purchase

Disease conditions	Therapeutic drug	Formulation	Strength and No.	Retail Price (Rs.)	TNMSC price (Rs.)	Price difference (%)
Cancer	Cyclophosphamide	Endoxan-N	50mg;10	36.35	13.218	275
Cancer	Fluorouracil	Fluracil	5ml	11.67	1.001	1166
Child and infectious disease	Chloramphenicol	Chloromycetin	250mg;10	30.76	4.4	699
Child health	Phenytoin Sodium	Dilantin	100mg;10	131.55	9.75	1349
COPD and Asthma	Betamethasone	Walacort	0.5mg; 10	3.55	1.043	340
COPD and asthma	Salbutamol	Asthalin	4mg;10	5.21	0.522	998
CVD	Verapamil	Veramil	40mg;10	5.02	4.392	114
CVD	Atenolol	Aten	50mg;14	25.75	1.2	2146
Diabetics	Insulin NPH	Actrapid	10ml	129.28	86.85	149
Diabetics	Glibenclamide	Daonil	5mg;10	6.60	0.454	1454
Injuries	Bupivacaine HCl	Sensorcaine	0.5%;20ml	34.34	15.5	222
Injuries	Ketamine	Ketalar	50mg;10ml vial	89.50	15.15	591
Japanese encephalitis	Ceftriaxone	Lyceft	1g;vial	90.00	16.11	559
Lymphatic Filariasis	Diethylcarbamazine	Banocide	50mg;10	3.88	0.707	549
Malaria	Chloroquine	Melubrin	250mg;10	4.36	2.233	195
Maternal health	Carboprost	Prostodin	1amp	80.13	68.5	117
Maternal health	Ferros Sulphate	Ferrocholate-Z	150mg;10	19.94	0.495	4028
Mental health	Chlorpromazine	Chlorpromazine-NP	25mg;10	5.95	1.81	329
Mental health	Alprazolam	Alprocontin	0.5mg;10	22.55	0.442	5102
Tuberculosis	Rifampicin	Rifacilin	150mg;100	99.68	66.6	150
Tuberculosis	Pyrazinamide	PZA-Ciba	500mg;10	42.46	5.188	818
Others	Rantidine	Consec	150mg; 10	7.51	2.205	341
Others	Dopamine	Dopinga	5ml	25.00	6.05	413
Others	Ciprofloxacin	Ciplox	200mg;100ml	27.00	6.41	421
Others	Paracetamol	Calpol	500mg;10	8.78	1.24	708
Others	Diclofenac Sodium	Diclonac	50mg;10	11.03	0.686	1608
Others	Diazepam	Calmpose	5mg;10	13.70	0.4	3425
Others	Dexamethosone Sodium Phosphate	Decdan	2ml	10.36	0.222	4667
Others	Cetirizine	Alerid	10mg;10	31.50	0.561	5615

Source: For Retail Price—Monthly Index of Medical Specialities, India, August, 2004
For TNMSC Price—Tamil Nadu Medical Services Corporation (TNMSC). Available from URL: <http://www.tnmisc.com/system.html>

control, etc.

The current funding of drugs in the Central and State Governments is reported to be grossly inadequate. For instance, in Orissa, the current level of spending per public institution is found to be extremely low: ranging from Rs 16,000 annually in PHCs to Rs 50,000 in CHCs (6-15 beds). At the secondary care level, with more than 30 beds, the amount spent for outpatient care works out to roughly Rs 0.50 per patient per day and Rs 9.50 per patient per day for inpatient care (Table 19).

It is clear that public institutions spend grossly inadequate amounts on drugs. Scaling up funds to increase spending on drugs is extremely important. At the same time, optimum utilization should be made of available resources. Efficient procurement policies have a significant bearing on ensuring the right medicines in sufficient quantities procured at lowest price to secure the maximum therapeutic value to the largest number of beneficiaries with the available resources.

An efficient procurement policy would have an integrated approach starting from (i) preparation of an essential drugs list, (ii) assessment of the quantity of drugs needed, (iii) quality assurance from suppliers, (iv) procurement process, (v) supply chain management, and (vi) prompt payment to suppliers.

In India, Central and State Government institutions follow one or more of these arrangements for public procurement: (i) Central Rate Contract System, (ii) Pooled Procurement either by the government or through an autonomous corporation, (iii) decentralized procurement, and (iv) local purchase.

The Tamil Nadu Medical Service Corporation (TNMSC) set up in 1994, is a pioneer in the current drug procurement and distribution system. The success of the TNMSC lies in its centralized drug procurement and distribution system supported by a computerized system of drug management.

The TNMSC has set up warehouses at all district headquarters from where supplies are provided to hospitals and other health

Table 19**Inadequate public spending on drugs in Orissa**

Level of public institutions	Amount (in Rs)
Public institutions (> 30 beds)	0.50 9.50
OPD (per patient per day)	
IPD (per patient per day)	
Block-level CHC hospital (16-30 beds)	110,000
PHC (6-15 beds)	50,000
Block-level PHC	30,000
Subcentres	16,000

OPD: outpatient department; IPD: inpatient department; PHC: public health centre

Table 20**Centralized procurement price: A comparison**

Drug	Strength and pack	Tamil Nadu		Delhi	
		1996	2003	1996	2003
Paracetamol	500 mg 10 tablets	1.18	1.12	1.24	1.17
Norfloxacin	400 mg 10 tablets	10.71	5.13	7.98	6.48
Rifampicin	450 mg 10 tablets	28.80	20.90	29.20	20.90
Chloroquine	250 mg 10 tablets	3.50	2.37	3.94	2.75
Gilbenclamide	5 mg 10 tablets	0.80	0.52	0.72	0.64
Atenolol	50 mg 10 tablets	1.36	1.04	1.45	1.55

facilities. A passbook system has been introduced where the entitlement of each facility is given in monetary terms. The institution can obtain any drug in the approved list if funds are available in the passbook.

The TNMSC has also developed a unique Drug Distribution Management System (DDMS) which is put to use in effective monitoring of procurement and distribution of drugs and supplies. Under this system, each district warehouse is linked by computer to the central computer in the Head Office. Receipt and issues of drugs have been computerized resulting in instantaneous adjustments to the stock position. This has facilitated movement of drugs from one warehouse to another based on needs, thus avoiding shortages.

Usually States adopt a 'two-envelope system' (technical bid and price bid being sent in separate envelopes). This system ensures a speedy and transparent mechanism in procurement of drugs. Contracts are awarded to only those manufacturing units, which have a Good Manufacturing Practices (GMP) certificate of the WHO and should ideally have a minimum ceiling of annual turnover.

Karnataka and Rajasthan, however, follow a decentralized system. In the former, a major part of drug procurement, accounting for 60%, is sourced by zila panchayats at the district level while the remaining 40% is sourced by government medical stores. In Rajasthan, in the order of priority, drugs are procured from public sector units (Rajasthan Drugs and Pharmaceuticals Ltd.). Tenders are invited only for those drugs not supplied by

Public Sector Undertakings and Small Scale Industries.

The direct benefits flowing from the TNMSC model seem to support lower prices contributed by competitive bidding and bargaining power. Table 20 illustrates the phenomenon of stable or declining prices due to centralized tender procurement of drugs. A simple comparison of drug price is carried out here, involving the procurement system in Delhi and Tamil Nadu, of drugs from different therapeutic categories with similar strengths and pack sizes. The analysis reveals that drug prices have tended to decline gradually or even steeply in some cases, during the period 1996-2003. The tender prices are not only declining but the analysis in the earlier section shows that even the initial price quoted is well below the market price, indicating a wide drug price difference. Further, the IT-driven logistics management system facilitates monitoring of procurement, distribution and issue of medicines. Quality control is achieved through building in quality requirements in the procurement process and drawing samples from each batch and testing them.

However, these developments and the success achieved by the States does not appear to have any impact on the Central Government, which continues to have multiple agencies for procuring and distributing drugs to its various health schemes/programme. This is depicted graphically in (Annexure I). While the Medical Stores Depot under the Ministry of Health and Family Welfare has seen gradual reduction in its handling of procurement and storage of drugs meant for a few States and paramilitary forces, drugs required under the Central Government Health Scheme (CGHS) are procured through the Hospital Services Consultancy Corporation (HSCC). Under the CGHS, orders for both generic drugs and proprietary drugs are placed through the HSCC. As expected, the price difference between generic and proprietary drugs is extremely high. It is a matter of concern that the Government of India, which brings out as Essential Drugs List covering only generic drugs is actually procuring and dispensing proprietary drugs for its employees under the CGHS scheme.

The total value of proprietary drugs is many times the value of drugs purchased by generic name. Second, the price difference not only results in sub-optimal utilization of resources but is also a major drain on Central Government resources. This discrepancy should be resolved and only generic drugs should be procured and distributed. There is no quality check on proprietary drugs whereas generic drugs are procured from prequalified bidders whose products are also subjected to sample testing.

Under different National Health Programmes (NHPs), the Central Government either provides financial aid or supplies drugs to States through centrally procured arrangements. Each of the six NHPs has its own procurement procedures resulting in duplication of effort with no attendant benefits of lower prices that a bulk purchase would entail. Currently, the NHPs are (i) Revised National Tuberculosis Programme, (ii) National Leprosy Elimination Programme, (iii) Reproductive and Child

Health (RCH), (iv) National Malaria Control Programme, (v) National AIDS Control Programme, and (vi) National Blindness Control Programme. The amount spent on drug procurement under the first three programmes worked out to Rs 480 crore during 2002-03. However, the procedures adopted in the procurement of drugs in this case appear to be a lengthy one with significant time over-runs. For instance, the action plan for procurement and supply of PHC kits under the RCH programme for the period 2003-04 had envisaged a time-frame of only nine months. However, procedural delays resulted in the entire process being completed in exactly double the time. Similar delays have also been observed in the procurement process involving another agency RITES, which deals with the Malaria Control Programme.

Much of these delays can be attributed to the absence of a system of pre-qualification of bidders. As a consequence, lower bids get rejected on the ground that the bidder does not have the required qualification or ability. In the absence of clear and well-defined criteria, the chances of an element of subjectivity in making decisions cannot be ruled out. The solution lies in introducing a two-envelope system, one on technical and another on price bids. Once technically unqualified bidders are rejected, the selection of the lowest bid becomes automatic.

Drug Regulation in India

In India, the drug regulatory system has been poor and neglected over the years, although much has been written and recommended by various committees. Poor enforcement mechanisms and multiple interpretations of the Drugs and Cosmetics Act 1940 have made regulation in this sector an unviable proposition (GOI 2003).

In some States such as West Bengal, Rajasthan and Punjab, there is no testing laboratory. Assuming a norm of one inspector for every 50 manufacturing units and one inspector for 200 sales units, the gap between the required norm and the actual number of available drug inspectors is woefully inadequate.

Given the currently available figure of 935 drug inspectors, one inspector serves around 320 wholesale and retail units instead of a norm of 200. This could be the reason why the number of spurious and standard drugs detected was relatively less. With adequate manpower and infrastructure, inspection of manufacturing and sales premises alongside a strong surveillance mechanism relating to the movement of spurious/counterfeit drugs could be carried out and unearthed more rigorously.

As far as the manufacturing units are concerned, the Government of India noted that roughly around 5900 units require intense surveillance/inspection and not all the 20,000 units (Mashelkar Committee Report 2003). Further, the Committee noted that the 1333 bulk drug units, 4354 formulation units, 134 large volume parenterals (LVP) and vaccine manufacturing units—accounting for 5877 units—are the ones that require intense inspection. The other major categories are cosmetics, loan licences, blood banks, etc. According to the

Mashelkar Committee, around 120 drugs inspectors are needed to monitor about 5877 units and another 100 inspectors are required for the remaining categories.

Other observations and recommendations made by the Committee are as follows:

- Strengthen the infrastructure and manpower relating to the monitoring/surveillance/inspection mechanism, both at Central and State level.
- Information received by the Mashelkar Committee reveals that only 17 out of 31 States has a drug-testing facility; of 17 only 7 appear to be 'reasonably equipped/staffed'.
- Measures are needed to tone up the Drugs and Cosmetics Act 1940, providing it with more powers (penalties) against manufacturers and distributors.
- The Mashelkar Committee proposes a Central Drug Administration (CDA) to be set up under the Ministry of Health and Family Welfare with autonomous status. The Committee recommended the setting-up of the CDA by the end of 2004 and State-level regulatory systems be strengthened accordingly.
- Review C & C1 licenses under the Drugs and Cosmetics Rules issued against manufacturing and distribution (wholesalers & retailers) to keep abreast with recent developments in the drugs sector.
- Review the Schedule H drugs which provides a list of prescription drugs.
- Comprehensively review Schedule K of OTC (over-the-counter) drugs.
- Curb inter-State movement of spurious drugs, tone up the existing communication network and freely exchange information between States.
- As far as the health food/therapeutic foods/dietary supplements are concerned, regulation relating to their quality and safety is needed as the demand for such products is increasing, and producers/sellers are indulging in exaggerated claims. These products should be brought under the purview of the relevant food law. However, any product that has 'distinct medicinal claims' would be qualified as a drug and not food products.
- There is a growing market for Indian Systems of Medicine (ISM), herbal products and drugs of natural origin. Concern has been voiced over their efficacy and quality. Efforts need to be made to update the requirements for licensing such products. Since for many such products long-term safety data are not available on their usage, additional safety data need to be obtained.
- The other area of concern is uncontrolled growth of medical devices and equipment. The standards and quality of many newly emerging equipment are questionable in nature.
- Clinical research is an area of concern as human lives in developing countries has become an experimental theatre for pharmaceutical firms. The Committee is of the firm opinion that responsibility must be shared between all concerned—investigators, sponsors, ethics committees and regulators. According to the Committee, 'It is absolutely essential to institutionalize Good Clinical Practices to achieve credibility for the data generated in India' (GOI 2003).

- Regarding Phase I clinical trials, the Committee accepted the revised Schedule Y, which stipulates that data generated from such trials in foreign countries need to be furnished to the Indian licensing authority and permission granted to repeat Phase I studies.
- As far Phase II and Phase III trials are concerned, the Committee observes that since the trials undergo rigorous review by the International Conference on Harmonization (ICH) signatory countries, approvals could be accorded and expedited by the regulatory authorities simply based on the technical documents submitted in ICH countries.

Drug patents in India

The Indian Patent Act, 1970

The Indian Patents Act, 1970 (effective since 1972) sought to provide only process patents for chemical substances including pharmaceuticals, agrochemicals and food products, and it granted product patents for non-chemical substances. The duration of process patents was fixed at seven years from the date of filling of the patent, or five years from the sealing of the patent, whichever is earlier.

Considering the importance of sectors such as pharmaceuticals, the Indian Patents Act, 1970 added a few provisions, which sought to significantly restrict the scope of protection. (i) Under the license rights, a process patent owner is obliged to sell the license to any third party fetching a maximum royalty of 4% in turn. (ii) The Government retained the right to issue compulsory licenses (after 3 years from the date of sealing of a patent) if the product under question was above 'reasonable' prices or if it did not satisfy public interests. (iii) Import of patent protected products is not considered to be 'working of patent' and therefore the patentee must necessarily produce the same in the country within three years from the date of sealing of a patent.

Patent protection under WTO, 1995

The Patents Act, 1970 has been instrumental in encouraging and developing the indigenous drug industry and indirectly containing medicine prices, but is currently under threat with the conclusion of the last Uruguay Round of General Agreement on Tariffs and Trade (GATT) negotiations in 1993 and the establishment of World Trade Organization (WTO) on 1 January 1995. In fact, extension of pharmaceutical product patents to all member countries was the key and controversial issue and also the last issue to be hammered out prior to tabling of the Draft Agreement at the end of 1991.

A gist of the patents system, 1970 and the change-over envisaged under TRIPS is given in Table 21. The erstwhile GATT (since 1995, WTO) sought to radically transform the patent Act in many countries. The specific article dealing with patents-Trade-Related Intellectual Property Rights (TRIPS)-requires that the signatories to GATT must necessarily amend their Constitution in accordance with this Article. The Article on TRIPS requires member countries to change their Act in such a way that they grant product patent to the pharmaceutical, chemical, food and agricultural sectors as well. The period of patent rights is to be changed in the Indian case from seven to twenty years. A proper amendment needs to be made to the Constitution of respective member countries amending the present rules. For developing countries, 1 January 2000 was fixed as the deadline for amending the Constitution. Developing countries like India have, however, been granted a five-year transition period till 2005. Until then, exclusive marketing rights (EMRs) would have to be granted to those companies introducing newly invented products. Domestic production of the patent-protected products is not mandatory wherein import is to be considered as a working of the patent. Even the Paris Convention specifically nails non-working or import of patent-protected products as an abuse of exclusive rights. The other retrograde step in the direction of TRIPS is the restrictions imposed on the free use of compulsory licensing provisions, which were hitherto

Table 21

A synoptic comparison of Indian Patents Act, 1970 and TRIPS, 1995

Different provisions of patent acts	Indian Patents Act, 1970	TRIPS-WTO, 1995
Type of patents	Only process patent allowed in the case of pharmaceuticals, chemicals and food	Product patent allowed in all sectors
Effective duration of patent	Seven years from the date of filing or five years from the date of sealing, whichever is earlier	Twenty years from the date of filing of patent application
Compulsory licensing	Compulsory licensing allowed after three years of sealing of patent if the price of product under question is above a reasonable level or if it did not satisfy public interests	Restrictive use of the provision of compulsory licensing - allowed only when there is national emergency/public non-commercial use/government use
Working of patent	Domestic production alone is considered as 'working of patent'	Whether products are manufactured locally or imported, it would amount to 'working of patent'
Burden of proof	In case of patent infringement, the burden of proof lies with the complainant of the patents	The burden of proof would fall on the alleged defendant of patent infringement

available in the present India Patents Act of 1970. The provision of compulsory licensing (under the new dispensation) can be harnessed only when there is a clear case of national disaster or calamity.

TRIPS and its likely impact

Several issues need attention in the wake of a change from process to product patent. These issues include price rise, market structure, foreign investment inflows, technology transfer, royalty and hence foreign exchange outflow, import-dependence, etc.

A sensitive and a highly controversial issue with regard to TRIPS is the concern about the high price of medicines. India was at the forefront in raising this issue backed by strong evidence. It is natural that many recent findings on this matter focused on likely price trends in India in the event of amending the present patents Act.

Lanjouw (1998) found drug prices in India, particularly in the post-patent 1970 period, among the lowest in world. As a sequel to a transition to the product patents regime, drug prices in India are expected to considerably escalate to a high level. Simultaneously, however, he and a few others (Vohra 1999) argue that given the current market conditions, it is estimated that only 10%–20% of the pharmaceutical products are under patent, and hence there is no need to focus on negative trends on the drug price front. It needs to be noted that once patented products start proliferating in the market, the composition of patented products in the total pharmaceutical market would undergo a drastic change in favour of the former. This would have a far-reaching influence on price.

Recent studies, mostly of simulation exercises carried out by Challu (1991), Nogues (1993), Fink (2000) and Watal (2000) all clearly show the extent of price increase that would be

likely in the near future with a changeover from the present system to a patent monopoly era. Table 22 provides a synopsis of each of these studies. The study by Fink (2000) suggests a surge in pharmaceutical prices in the range of 9%–76% if product patent rights are introduced. However, as far as the impact on various therapeutic categories is concerned, the upsurge in price would depend on the demand for new patented products or on the available alternative treatments, whichever dominates the market. Interestingly, Fink suggests that rapid acceleration in drug prices could be countered by various price control measures available with the local government, a provision allowed in the TRIPS agreement. Compulsory licensing is another tool to counter the adverse implications of conferring patent protection.

Price ceilings, if put into effective practice, by allowing firms to charge normal profits in addition to production costs, would reduce or eliminate an inventor's patent-induced market power, argue Braga et. al. (2000). They further assert that when normal profits are granted the potential disincentive to invest would wither away resulting in recouping of R&D investment.

In any case, the price of patented products is bound to be high. This could be because of several reasons: (i) formulation activity would be costly as multinationals would normally set high prices for the bulk drugs imported in view of global reference pricing; (ii) issuing compulsory licensing to any company in India would amount to enormous royalty fees, in return. This would naturally be reflected in the base price of the patented products; (iii) any effort to locally produce the patented medicine is nothing but monopoly production and consequently monopoly pricing, which will always be higher than the competitive price.

However, a point worth noting in this context is that one must actually analyse the entire gamut of issues related to the pharmaceutical market and one cannot merely take such

Table 22

Summary of Studies: Simulation exercise on pharmaceutical product patents and their impact

Studies	Price	Capital Transfer	Welfare Loss/Gain
Challu (1991) (Argentina)	Estimated price increase for the market segment subject to patents: 273.2%.	Money transfers abroad: US\$ 367 million per year	Consumer welfare loss: US\$ 309 million per annum
Nogues (1993) (developing countries)	-	-	The losses from consumer misallocation could be as high as US\$ 7.7 billion
Fink (2000) (India)	Given different demand and substitution elasticities, the lower priced among quinolones such as ciprofloxacin, the price could range from 233.5% to 276.7%, while for the highest, such as ofloxacin, it could range from 318.6% to 370.5%.	-	Taking the case of quinolones, welfare losses range from US\$ 28.7 million to US\$ 69.9 million per annum, assuming certain elasticity
Watal (2000) (India)	The price rise could be as high as 242% with a constant elasticity-type demand function.	-	Moving from current market structures to patent monopoly could yield a loss of US\$ 140 million annually

provision as given. An appreciation of the overall structural adjustment in economies such as India show that over the years, particularly since the early 1990s, pharmaceutical prices have been decontrolled to a substantial degree and in fact presently only a few drugs (75 essential drugs in 1998) are actually controlled. Many more of these are likely to witness lifting of controls in the immediate future, as made evident in the intentions of government policy pronouncements (GOI 2001).

Compulsory licensing and parallel imports

Merely ten years after the establishment of WTO, the darker side of TRIPS is unfolding before the world. There has been perceptible damage to public health particularly in many developing countries. The controversy over accessibility of cheap drugs to combat HIV/AIDS in Africa and other developing countries has put the TRIPS agreement under vigilance. In 2000, Brazil was taken to the Dispute Settlement Mechanism of WTO for the alleged violation of TRIPS by the US and the next year saw 39 drug MNCs aligning against the South African Government for not conforming to the new global patent regime. The AIDS epidemic has assumed serious proportions triggering off national emergencies, particularly in the African countries, in which 2.5 crore people are infected with HIV. The South African government pressed into service the provision of compulsory licensing and parallel import under its new patent regime. Accordingly, this provision enabled the South African Government to either direct domestic companies to manufacture or import cheap branded generic drugs from developing countries such as India.

Western pharmaceutical companies have been marketing a cocktail of antiretroviral drug therapy at unaffordable prices in many developing countries. With the arrival of Indian generic substitutes, drug multinationals raised a protest. For instance, Cipla was the first to enter the African market with its triple drug cocktail (Hindu, 16 May 2001) of antiretrovirals-lamivudine, stavudine and nevirapine—offering it at a price of US\$ 350 per patient per year, a small fraction of the US\$ 10,000 that a western patient pays. An unimaginably high price in developed countries and an on-going competition fostered by generic varieties in South Africa has brought prices tumbling down. Intriguingly, despite an offer of knock-off versions at rock-bottom prices, market prices are far beyond the purchasing power of an average African. Drug MNCs initiated action against the South African Government. A spirited national and international challenge was mounted on these companies, which forced them to make a tactical retreat.

Another controversial case involves Brazil. Its newly amended patent policy allows for local production by providing license to domestic companies if the foreign-patented products are not produced locally. The Brazilian patent law requires a foreign patentee to manufacture a product locally within the stipulated three years of the grant of patent. Importing such patent-protected products is not considered to be 'working of patents' in Brazilian law. Under this provision, Brazil recently allowed domestic production of generic anti-HIV/AIDS drugs, which has been contested by the US. With the heat of international pressure mounting heavily on the US, it withdrew the case reg-

istered at WTO against Brazil (The Hindu, 26 June 2001).

Stung by increasing criticism and battered image, drug multinationals have subsequently joined the race to slash anti-AIDS drug prices. This move is, however, seen as a ploy to retain their market share, which is threatened by inexpensive generic competition. Merck and other five multinationals (The Hindu, 16 May 2001) have since come forward to sell antiretroviral drugs at lower prices to developing nations.

It is argued that TRIPS allows for certain flexibility in its clauses to protect public health. The monopoly abuse of the patent system that emanates from exclusive rights conferred on the patentee could be controlled or restricted by means of resorting to granting compulsory license or through parallel imports. The principles articulated under Article 8 and Article 31 of the TRIPS agreement (www.wto.org/english/tratop_e/trips_e/trips_e.html) appear to enable member countries to adopt measures that would safeguard them in the event of public health emergencies. The specific instances under which compulsory licensing could be conferred are:

- (i) insufficient or non-working of patents;
- (ii) failure to produce locally and therefore continuously import the product even after the issue of patent for 3-4 years;
- (iii) in the event of charging an unreasonably high monopoly price.

Unfortunately, it took years for many developing countries to realize and challenge the lethal provisions of the TRIPS agreement. The toll and suffering that the AIDS epidemic inflicts on impoverished Third World nations triggered the latest patent battle. It needs to be reiterated here that apart from the devastating AIDS pandemic, there are other killer diseases in countries such as India (diarrhoea, malaria, TB, etc.) which require immediate attention and pose a continued threat to health security.

Data exclusivity

Article 39.3 of the TRIPS agreement requires that member countries safeguard the interest of inventing companies from unfair commercial use of products arising out of disclosure of data submitted by the companies. However, TRIPS allows for exception to this rule. Member countries can waive this article to protect public health exigencies and thereby grant generic manufacturers the opportunity to produce drugs thereby limiting 'evergreening' of patents.

In pharmaceutical industry parlance, data exclusivity is one in which the originator company registers with a regulatory authority of a country by submitting data demonstrating the safety, quality and efficacy of the innovative drugs. However, the generic manufacturer need not get such an approval, as, while applying for approval of their drug, they refer to bioequivalence data already established by the originator. If data exclusivity are granted for a specific time period, it would deny the generic manufacturer from availing the reference data of the originator. The period of data exclusivity ranges from five years in the US, six to ten years in the EU, etc.

Indian Patents (Amendment) Bill, March 2005: Significance and implications

India has moved into a product patent regime in 2005 complying with the TRIPS provisions of WTO. In a series of amendments to the Indian Patents Act, 1970, the latest and the crucial amendment to the Act was made in March 2005. The new Indian patent amendment suffers from ambiguity, technical loopholes and fails to incorporate some of the flexibilities incorporated in the TRIPS regime. This has serious implications for access to drugs and medicines in India, and the developing world in general. The issues that still need to be addressed in the newly amended patent acts are: (i) issues relating to the scope of patentability; (ii) cap on royalty payments; (iii) plugging all ambiguities and technical loopholes in the amendment to avoid unnecessary and expensive litigation in the future; (iv) vesting discretionary powers in the patent office in terms of timelines of rules, making them vulnerable to vested interests. Let us discuss each of them in detail.

Definition and scope of patentability

The new amendment does not clearly state 'what is patentable'. In the amended Act, pharmaceutical substances are described as 'any new entity involving one or more inventive steps'. This could mean anything involving formulations, pharmaceuticals, isomers, polymorphs and their combinations. Ideally, and for practical purposes, it should have been 'new chemical entity'. While the Indian Patent Act, 1970 clearly defined the terms 'invention', 'patents', 'inventive step', and 'industrial application', the new amendment suffers from ambiguity and leaves several loopholes in defining these terms. The other criterion for patentability in the new Act, namely 'inventive step', unnecessarily broadens the scope. Accordingly, the patentee is either required to display that the invention incorporates a technical advance or has economic significance, or both. Thus, by simply showing economic significance of an inventive step over technical advance, patent holders get the benefit of this broad and ambiguous definition.

Compulsory Licensing

One of the central themes of the Doha Declaration is the issue of compulsory licensing. Patent monopoly abuse is sought to be restricted by issuing a compulsory licence to a generic producer in the pharmaceutical market. The Doha Declaration reaffirmed the members the right to protect public health and extolled the members to interpret and implement TRIPS, which would help them promote access to medicines for all. According to the newly amended patent Act, a compulsory licence can be issued only during a national emergency, extreme emergency or public non-commercial use, and it will be issued only after three years from the date of grant of the patent. By leaving out the grounds on which a compulsory licence can be issued, the bill barter away the flexibility brought in during the Doha Declaration.

Cap on Royalty Payments

Another related issue with compulsory licensing is the cap on remuneration to the patent holders. The amended Act leaves open this issue and assures 'reasonable royalty' to the patent monopoly. In many countries, there is a cap on royalty payments made to the patent holders, say 4% of the total turnover of the medicine. Patents monopolies can simply refuse to issue compulsory licensing by demanding excessive royalty payments. What constitutes 'reasonable' is only to be decided in the court, multiplying litigations.

Mailbox Products

Product patent regime, all over the world, thrives on frivolous claims for 'me-too' drugs of similar chemical entities. This is clearly in evidence before the advent of product patent regime in India. Under the mailbox provisions (India is accepting applications for product patents in the areas of pharmaceuticals and agrochemicals since 1999, although not granted any patents since the amendment was made only in March 2005), there were reportedly 4792 applications for product patents although during 1995-2004, only 297 new chemical entities have been bestowed with product patent status in the world. It is therefore clear that the rest of the applications for patents are only frivolous in nature. Moreover, according to the amended Act, any generic producer who were manufacturing these mailbox products, before January 1, 2005 can continue to produce such medicines but are required to pay 'reasonable royalty'. Accordingly, the generic manufacturers were required to show that they made 'significant investment' in their venture. This ambiguity is likely to throw up infringement suits and more litigation.

Pre-grant and post-grant opposition

Through the present amended Act, initiation of opposition proceedings against a grant of patents is allowed only by way of 'representation' and not in the form of notice. Further ambiguity is reinforced as it is unclear whether access to documents of patent holder is possible. If not, how will any opposition proceedings be carried forward or to start the process?

Policy suggestions

Out-of-pocket spending on drugs by households in India is extremely high. Given the low purchasing power of the population, virtually no health insurance in place and with an inadequate and malfunctioning public health institutions, the need of the hour is to focus on the following:

- The present list of drugs under the DPCO, 1995 needs to be expanded by including all the drugs under the Essential Drugs List. The criterion of essentiality must form a vital part in deciding whether a drug is to be included in the controlled category or not.
- The Indian pharmaceutical market is flooded with irrational drugs (particularly combination products). Estimates sug-

gest that there are about 20,000 products in the market. With barely 300-plus drugs recommended by the WHO and 268 in the Essential Drugs List as proposed by the Government of India, 2003, it would be entirely possible to tackle all disease conditions in the country. In one stroke, all combination products could be wiped out by a government edict. Towards this goal, a committee of physicians, pharmacologists, microbiologists, etc. should be appointed to review irrational combination drugs.

- It is absolutely essential to encourage only generic drugs.
- Formulation of standard treatment guidelines is imperative in the backdrop of an essential drugs list. Moreover, a National Formulary updated on a two-yearly basis also needs to be put in place. We also recommend that a National Antibiotics Committee be set up and continuous surveillance ensured on the availability of antibiotics.
- Manufacturers and retail pharmacy stores may be provided with a variety of incentives to produce and sell essential drugs. Fiscal incentives such as lower duty, subsidy, etc. could be provided. For instance, in the post-April 2005 period, a VAT of 4% is being proposed on drugs and medicines. Although 4% could be levied on other inessential drugs, essential drugs could attract a minimum of 1% VAT.
- Since trade margins are exorbitantly high in the drug industry, fixing ceilings on trade margins is necessary. Currently, price-controlled drugs under the DPCO, 1995 attract 8% on wholesale and 16% on retail. This margin can continue at this rate and uncontrolled drugs should also be brought within the purview of margin ceilings. As suggested by the interim report of the Sandhu Committee (Government of India 2004) we propose wholesale and retail margins on branded drugs to be 10% and 20%, respectively. On generic-generic drugs, the respective margin could be 15% and 35%. This should be inclusive of various trade discounts offered to dealers.
- Monopsony purchase can check exorbitant profit and trade margins of drug corporates. Centralized public procurement is definitely a way to save the public exchequer.
 - i) As a first step, procurement of drugs meant for all Central Government health programmes and health facilities of different ministries and other autonomous bodies need to be centralized. Health institutions under the Central Ministry must strictly dispense only generic drugs and do away with proprietary drugs.
 - ii) The success of the TNMSC in drug procurement could be replicated in other States as well. During 2003-04, with a total budget of around Rs 120 crore, the TNMSC served nearly 11,000 medical institutions (from medical college hospitals to subcentres, including autonomous institutions and other departments in the State). The administrative cost involved in running TNMSC is in the range of 0.5%-1%. By simply procuring in bulk and streamlining the procurement system, the present budget spending on drugs could save huge resources. This would enable States to procure more and make them available to the needy.
- Drug regulation has become a complex and neglected

issue over the years in India. Strengthening the drug regulatory authority, as prescribed by the Mashelkar Committee, is the need of the hour. The drug regulatory authority could be provided with an autonomous status to ensure transparency and effective functioning. To this end, we suggest that the government set up a National Drug Authority (NDA) with an autonomous status to take up the functions of drug pricing, quality, clinical trials, etc. Consequently, the present National Pharmaceutical Pricing Authority (NPPA) could be merged with the proposed NDA. For strengthening the drug regulatory system as suggested by the Mashelkar Committee, the Central Government needs to allocate Rs 1.6 crore annually for the additional posts (mostly inspectors) that would be created and another Rs 50 lakh as contingencies for the creation of additional offices.

- While the Essential Drugs List is prepared by the Ministry of Health and Family Welfare, the Ministry of Chemicals and Fertilizers is involved in formulating and exercising price controls on drugs. For an integrated approach, it would be a better idea to transfer the functions of both the ministries relating to drugs to the proposed NDA. The NDA must make efforts to collect, tabulate and disseminate data on drug production, therapeutic-wise sales, company level information on drugs, etc. It is absolutely essential for the government to collect such data.
- To ensure a transparent mechanism for new drug approvals, a Public Hearing could be organized involving physicians, pharmacologists and specialists in that specific therapeutic group by the drug controller. The drug company could be requested to furnish data indicating with which of the existing drugs the new drug has been compared in clinical trials and provide justification for the introduction of the new drug. This would ensure that the new drug in question is not only safe but also less expensive than the existing ones.
- The new Indian Patent (Amendment) Bill, March 2005 which was passed by Indian parliament suffers from ambiguity, technical loopholes and still fails to incorporate some of the flexibilities incorporated in the TRIPS, WTO regime. This has serious implications for the access to drugs and medicine in the country in specific and to the developing world in general.
- The amendments need to clearly spell out the scope of subject matter on patentability.
- The question of 'reasonable' royalty to be paid on the issuance of compulsory licensing should be stated upfront and specific by indicating a cap on royalties to be paid to the patentee, say 4% of the total turnover in a year.
- For the 'mailbox' drugs introduced post-1995, the Government need to specify what constitutes 'significant investment' for the Indian companies manufacturing these drugs otherwise it may lead to unnecessary litigation.
- Government should consider incorporating in the immediate future, mechanism for automatic compulsory licensing. Given the fact that the Indian Patent Offices suffer from lack of adequate manpower and infrastructure, the discretionary powers vested on the patent office in terms of timelines of Rules could make the patent office vulnerable to vested interests. This is because Rules can be amended as and when

the patent office deems it fit leading to excessive discretionary powers. We recommend therefore that the rules be made more

transparent and at the same time strengthen the Patent Office in order to carry out its duties more efficiently.

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Annexure 1

