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Who Benefit From Essential Drug Price Control, Need of Price Control In India -A review

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Abstract: As countries become wealthier, they typically experience an epidemiological transition and pressures on public healthcare budgets grow, with healthcare commodities, especially pharmaceuticals, contributing a large share of increases in both government and individual household spending. Procurement effectiveness and efficiency become, therefore, all the more important, with pharmaceutical and device pricing policies central in national and global strategies for healthcare system reform and strengthening. India is one of the developing countries. A substantial proportion of population of this country is largely exposed to the drug market whose purchasing power is extremely low. Around 42% population of this country lives under the National poverty line ($1.9 per day). Vital issue concerning them is to access the health care facility at an affordable cost. Medicine is a part of health care cost and it costs to around 70% to 80% of total cost. Thus, cost of medicine is a governing factor of health care system especially when it comes to price control of health care facilities. To bring down the cost of health care facilities, government spends money for health care facilities. A comparative expenditure made by state government is depicted in this article. NPPA (National Pharmaceutical Pricing Authority) is the Indian pharmaceutical pricing regulating authority and it achieves its objectives by implementing the DPCO (Drug Pricing control order). In spite of existence of the DPCO, drastic price variation is observed between the products of same API (Active Pharmaceutical Ingredient) and several factors are responsible for the same. To overcome the stated problem and monopolistic trade practice by patent holder/brand manufacturer, TRIPS (Trade Related Intellectual Properties Rights) provides Compulsory Licenses which has its unique role to play in affordability of medicines. This study will thus try to justify the need to bring NLEM Indian pharmaceutical sector is rising very rapidly and there is a want of regulatory affairs.

Keywords: : Essential medicine, NPPA, DPCO, NELM, EDL, TRIPS, Pharmaceutical Industry, Lmic,WHO

Introduction: India is one of the developing countries. A substantial proportion of population of this country is largely exposed to the drug market whose purchasing power is extremely low. (1) Around 42% population of this country lives under the National poverty line ($1.9 per day). (2) The concept of essential medicines, first introduced by the World Health Organization in 1977, has been adopted by many countries including India. This concept has produced NLEM (National List of Essential Medicine) that includes the most cost-effective medicines for a

particular indication. Essential medicines are those that satisfy the priority healthcare needs of the majority of the population. The list is specific to India and addresses the disease burden of the nation besides being the commonly used medicines at primary, secondary and tertiary healthcare levels. The latest NLEM of India has come in 2015 and it contains 376 medicines which cover 209 formulations, including 16 fixed dose combinations. These drugs are considered to be adequate to meet the common contemporary health needs of the general population of the country. At present, the government, through the National Pharmaceutical Pricing Authority (NPPA), controls prices of 74 bulk drugs and their formulations.(3) Drug prices have shot up phenomenally in India over the past decade and a half. There was a nearly 40% rise in all drug prices between 1996 and 2006. However, during the same period, the price of controlled drugs rose by 0.02%, while those in the Essential Drug List (EDL) increased by 15%. The price of drugs that were neither under price control nor under the EDL grew by 137%. Once these essential medicines are brought under Drug Price Control Order (DPCO), it cannot be sold at a price higher than that fixed by the government. This will put a cap on the maximum price at which essential drugs, like some commonly used anti-AIDS and anticancer drugs, besides a horde of painkillers, anti-TB drugs, sedatives, lipid lowering agents and steroids, can be sold in the country. Lack of access to much needed medicines may be due to high costs of the drugs, low purchasing power or non-availability. Each of these elements which result in poor access should be analysed for better access of the drugs.

History of Drug Price Regulation

In 1955, India established the Essential Commodities Act, which allowed regulators to control prices of consumer products under Section 3. Under the Essential Commodities Act, drug prices have been controlled using a series of Drugs Price Control Orders (“DPCOs”), beginning in 1970. Under a DPCO issued in 1995, India established the National Pharmaceutical Pricing Authority (“NPPA”), an organization which has limited ability to review and fix pharmaceutical prices (Narula, 2015). Under the

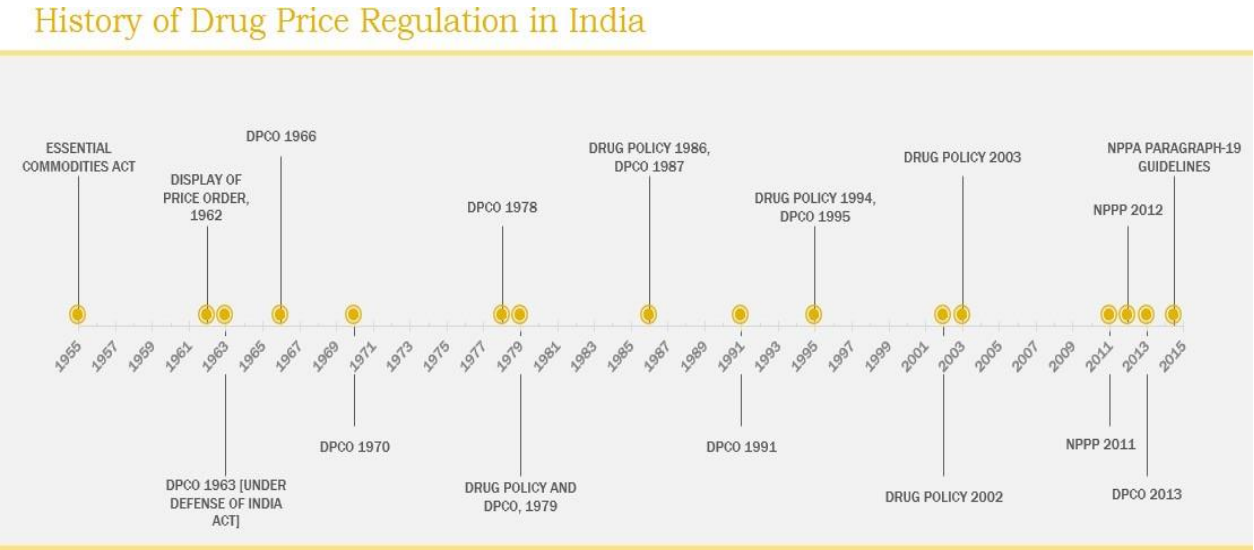

FIG:1 Timeline of Drug Price Regulation in India Between 1955 to Present

most recent DPCO, issued in 2013, the NPPA has authority to maintain and expand the National List of Essential Medicines ("NLEM"), a list of medications based off the World Health Organization's list of essential medicines and place drugs on this list under price controls (Narula, 2015).

Expenses on Medicines

Health care expenses are composed of medicines, diagnostic charges, analytical testing and other expenditures. Out of these all categories, expenditure on medicines carries largest portion around 70% to 80% of health care expenditure (Table 1). Hence, controlling medicine prices result into decreasing cost of health care facilities.

Quintiles	Health Exp. (Rs)		Exp. on Medicine (Rs)		% Exp. on Medicine	
	Rural	Urban	Rural	Urban	Rural	Urban
First (Lowest)	7.72	11.71	6.68	9.91	86.47	84.60
Second	13.79	21.66	11.71	17.49	84.89	80.71
Third	19.61	29.73	16.46	22.72	83.94	76.44
Fourth	29.98	47.00	24.44	34.34	81.53	73.05
Fifth	77.47	105.67	55.46	65.90	71.59	62.36
Total	29.58	43.27	22.85	30.14	77.24	69.66

Source: *Computed from NSS Report 461, 55th Round*

Health care expenditure

Here, population is divided in five categories (rural and urban areas) on the basis of income and categorised in ascending order of income. Table 1 shows overall health expenditure, expenditure on medicine and % expenditure on medicines to health expenditure. As per percent expenditure on medicines, 77% of health expenses in rural area and 70% in urban area are on medicines alone. Interpretation of above statistical data directly indicates that as the people are poorer, expenses on medicines are larger out of all possible health care expenses.

Government Drug Expenditure

Government is also trying to market health care facilities affordable to the patient by spending money in it. Systemic approach toward the health expenditure by government is responsible to get perfect outcome. Present statistical data shows government is expending money in health care facilities, approximately 10% of which is spent on medication expenses (Table 2). (4)

States	Drugs expenditure (Rupees)	Health expenditure (Rupees)	% of Drugs to Health
Andhra Pradesh	1270.45	13142.40	9.67
Assam	153.01	3269.08	4.68
Bihar	220.31	7134.84	3.09
Chhattisgarh	250.26	2258.71	11.08
Gujarat	269.38	7154.79	3.77
Haryana	309.61	3147.09	9.84
Karnataka	778.39	9863.31	7.89
Kerala	1242.06	7293.15	17.03
Maharashtra	2030.59	17837.95	11.38
Madhya Pradesh	792.19	6668.93	11.88
Orissa	213.02	4213.57	5.06
Punjab	91.63	6182.64	1.48
Rajasthan	904.50	9731.16	9.29
Tamil Nadu	1809.72	11843.28	15.28
Uttar Pradesh	710.42	13557.88	5.24
West Bengal	579.84	13194.83	4.39
Central Government*	7264.92	59770.00	12.15
All-India	18890.38	1962636.86	9.63

Source: Budget Documents, Respective States & Central Govt.

* Many states report drug expenditure under the category of Materials and Supplies.

State wise government drug expenditure

Drug procurement in India is done largely by the government. However, it is not more than 10% of the overall expenditure on health. The overall expenditure on drugs spent by the GOI (Government of India) in 2008 stood at Rs.18,890 crore vis-à-vis a total expenditure of 19,62,636 crore spent on health. This represents 9.63% of total health expenditure spent on drugs.

Here, in table 2 comparative drug expenditure by state governments is tabulated and percent of drugs to health is also calculated and it helps to understand that which state is doing well in comparison to others. The study shows that government of Kerala and Tamil Nadu are having better expenditure plans compared to other state governments.

NPPA and DPCO

- NPPA is an organization of the Government of India which was established, inter alia, to

fix/revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country, under the Drugs Prices Control Order, 1995.

- The organization is also entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs from the consumers.
- It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

Functions of NPPA

- To implement and enforce the provisions of the Drugs (Prices Control) Order in accordance with the powers delegated to it.
- To deal with all legal matters arising out of the decisions of the Authority.
- To monitor the availability of drugs, identify shortages, if any, and to take remedial steps.
- To collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc, for bulk drugs and formulations.
- To undertake and/or sponsor relevant studies in respect of pricing of drugs/ pharmaceuticals.
- To recruit/appoint the officers and other staff members of the Authority, as per rules and procedures laid down by the Government.
- To render advice to the Central Government on changes/revisions in the drug policy.
- To render assistance to the Central Government in the parliamentary matters relating to the drug prices.

Recent policy changes have enormous implications for drug prices in India. As of today, only one-tenth of drug market is price controlled as against nearly 90 percent during the late 1970s, this has triggered wide debate on the rising drug prices.(6) Prices of drugs in India were considered to be one of the highest in the world in 1960.(7) The trend of high prices has tended to reverse since the 1970s in the wake of a series of policy measures, such as, drug price control, process patents for drugs, etc. Over the years, however, price controls are being dismantled gradually and the number of bulk drugs that were under price control has been brought down gradually to a very minimum level. In 1979, 347 bulk drugs were under the price control, which came down to 166 in 1987 and further reduced to 142. Drastically pruning the list of drugs under control further, the Drug Price Control Order (DPCO) of 1995, sought to limit the control to just 76 drugs. The DPCO delineates certain benchmarks on which price control is based. These are i) sales turnover, ii) market monopoly and iii) market competition.

The sharp rise in drug prices could also result from high and growing trade margins. It must be noted that not only there is a general rise in pharmaceutical prices; the initial price *per se* is fixed with enormous margins. Trade margins are one of the highest in the pharmaceutical industry (Sakthivel 2005 and Srinivasan 1999). Add to it, the extra sales taxes levied by respective state governments – since drugs come under state subject.
drug formulations that are under price control are those that have i) annual turnover of Rs. 40 million and above with monopoly scenario (see chart 1 for detailed criteria) and ii) annual turnover of lessthan Rs. 40 million but not less than Rs. 10 million with less market competition. Across the board, the price control order of 1995 fixed

100 per cent Maximum Allowable Post- Manufacturing Expenses (MAPE) to all drugs The retail price of the formulation is calculated based on the following formula:

Retail Price = (M.C + C.C. + P.M. + P.C.) x (1+MAPE/100) + E.D.

Where,

M.C denotes material cost including drug cost and other pharmaceutical aids;

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

DPCO Year	DPCO 1979	DPCO 1987	DPCO 1995	DPCO 2008	DPCO 2013
1. No. of Medicines under Price Control	347	142	76	74	348
2. No. of categories under which the above medicines were categorized	3	2	1	1	3
3. MAPE % allowed on normative/ National ex factory costs to meet post-manufacturing expenses and provide for margin to the manufacturers.					
Category I	40%	75%	100%	100%	35%
Category II	55%	100%	N.A.	N.A.	60%
Category II (Single ingredient Leader products)	100%	N.A.	N.A.	N.A.	100%

Table 3: Comparison of Drug Price Control Order

DPCO provides power to fix ceiling price to fix formulation prices, to fix ceiling price, to recover dues, to recover overcharged amount, to entry, search and seizure and to review, to issue guidelines and directions, to exempt.

The Pricing of Bulk Drugs

The 76 bulk drugs (Now 74 drugs as Amikacin Sulphate and Mefenamic Acid were omitted by S.O. 626(E) dated 2/9/1997) (3), the prices of which are controlled under DPCO 1995, have been enlisted in the First Schedule annexed to the order. As per para 3 of DPCO, 1995 prices of scheduled bulk drugs are fixed by the NPPA to make them available at a fair price from different manufacturers. These prices are fixed from time to time by notification in official gazette. Each company submits to the government, a detailed working of the prices of various bulk drugs that it requires. The prices submitted by the companies are such that the allowed profitability parameters are achieved. The government subsequently studies the

applications made by the major players for every bulk drug and cost audits reports ofmanufacturers, before arriving at the final price. Following steps are involved in fixation/revision of bulk drug prices :-

Step 1: Identification of bulk drugs:

Bulk Drugs are taken up for study on following basis:-

- Whose validity period is due to expire?
- Request from the concerned manufacturer/company.
- Drug produced in the country for which no price has been notified under DPCO, 1995.

Step 2: Collection of data:

Data is collected by issuing questionnaire/Form I of DPCO, 1995/cost-audit report etc. and verification by plant visits, if required.

Step 3: Preparation of actual cost statement:

Actual cost for the year for which data is submitted is prepared based on data submitted / collected & verified during plant visit

Step 4: Preparation of Technical Parameters:

Technical parameters are prepared based on data submitted, collected and verified during plant visits. Plant capacity is assessed considering 330 working days for normal operation of plant leaving 35 days for scheduled maintenance of plant. The achievable production level is considered at 90% utilization of assessed capacity allowing 10% production loss on account of unforeseen break down and non-scheduled maintenance.

Step 5: Preparation of Estimated Cost:

The estimated cost for the pricing period are then prepared based on actual cost & the technical parameters. While projecting the future cost, an increment is recognized at 5% per annum in respect of salaries & wages. Wage agreement, if any, which has been finalized and signed is also recognized while preparing the estimates. In respect of other overheads of fixed/semi variable nature, increase at 2.5% per annum is made to cover the normal incremental effects. The customs duty and other taxes as per the current budget are considered.

Step 6: Calculation of Fair price of bulk drug:

Fair price is calculated by providing returns as specified in sub para (2), para 3 of DPCO, 1995. (8) While fixing the maximum sale price of the bulk drug, a post-tax return of 14% on net worth or a return of 22% of capital employed or in respect of a new plant an internal rate of return of 12% based on long term marginal costing is considered depending upon the option exercised by the manufacturer of the bulk drug. In case, the production is from basic stage, additional 4% return is considered on net worth/capital employed.

Step 7: Fixation of maximum sale price of the drug:

When the number of manufacturers of the said drug is more than one, the maximum sale price

is fixed at 2/3rd cut off level or weighted average price, depending upon the situation.

Step 8: Notification of bulk drug price in official Gazette.

After calculating the maximum sales price of the bulk drug, it is notified in the official Gazette.

Conclusion

In its present form, DPCO is ineffective as it is inadequate in its coverage and do not serve its purpose to required extent. There is an urgent imperative to spruce up the existing criteria for price control. The present practice of using monopoly and market dominance measures need to be replaced with the criteria of 'essentiality' of drugs. This would have maximum spill-over effect on the entire therapeutic category. This is also likely to prevent the present trend of circumventing price controls through non-standard combinations and at the same time would discourage producers moving away from controlled to non-controlled drugs. Direct price control should be applied on formulations rather than basic drugs. This is likely to minimize intra-industry distortion in transaction. Finally, we argue that to ensure drug security in India, a strong regulatory institutions need to be established or already existing regulatory institution should be empowered.

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