

Original Research Article

Cost comparison of antihypertensive drugs available in India with Drugs Prices Control Order price list

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Received: 06 December 2018

Accepted: 14 December 2018

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ABSTRACT

Background: DPCO (Drugs Prices Control Order) price list is issued by NPPA (National Pharmaceutical Pricing Authority) each year to guide the pharmaceuticals companies for controlling the prices in India. Some drugs cost more than the DPCO list. As antihypertensive drugs are taken lifelong once diagnosis is made, price variation and costing above prescribed price cause a huge economic burden on such patients. This study was undertaken to know the number of antihypertensive drugs brands with price above the recommended DPCO price list 2017.

Methods: Authors have collected the data from website medguideindia.com, CIMS (current index of medical specialties), Drug Today, and compared the listed antihypertensive drugs of various available brands in India with DPCO price list 2017. Data was entered in Microsoft excel 2010. Percentage of selling price above the DPCO price list was calculated for each drug.

Results: The data of 30 formulations of 16 antihypertensive drugs was analysed. The total number of available brands of all formulations was 1365 out of which only 831 (60.88%) brands were found to have price <DPCO recommended list. 534 (39.12%) brands had price more than the recommended limit. The minimum violation of price limit was found in case of metoprolol 25mg (6.66%) and maximum price violation was observed with spironolactone 25mg and sodium nitroprusside inj 10mg/ml.

Conclusions: Reassessment and monitoring for implementation of DPCO price list should be done as still large number of brands are not following the regulations and are violating the limit set by NPPA/DPCO.

Keywords: Antihypertensives, Drug price, DPCO, NPPA

INTRODUCTION

Prevalence of hypertension in India is 29.8%.¹ With more than 20000 pharmaceutical companies, by sales volume India stands 3rd in world with annual turnover of 22 billion dollars. India is a manufacturing hub for drugs, exporting medicines to almost every country in the world.² But at the same time this leads to a great price variation. As antihypertensive drugs are taken lifelong, a little price variation results in a huge economic burden on

patients with lower socioeconomic status of developing countries. In India, more than 80% of healthcare expenditure is borne by patients.³

In 1997 NPPA (National Pharmaceutical Pricing Authority) was established for ensuring availability and affordability of the drugs. The drug price control order (DPCO) 2013 is one such effort under NPPA. DPCO was implemented by the government with the aim of bringing down the cost of essential medicines. Price list of

essential medicines is issued by NPPA each year to guide the pharmaceutical companies for controlling the drugs prices in India. It fixes the ceiling price of a scheduled formulation of any brand or generic drug of a pharmaceutical company having more than or equal to 1 percent share in the market.⁴

Ceiling price is calculated as:

Ceiling price = average price to retailer X (1 + percentage of margin to retailer)

Ceiling price of a new drug is calculated on the principle of Pharmacoeconomics on the recommendation of a standing committee of experts.

When any pharmaceutical company launches new drug, whether branded or generic it should be below or equal to the ceiling price fixed by the government for that specific formulation. If a drug manufacturer is selling a drug at higher price fixed and notified by the government, the manufacturer has to modify it within 45 days and the overcharged amount with interest has to be deposited to government in addition to penalty. However pharmaceutical companies can increase the drug price annually in the month of April depending upon the wholesale price index. But it is found that some brands available in the market are sold above the prescribed limits. This study was undertaken to evaluate the number of antihypertensive drugs brands with price above the recommended DPCO price list 2017.

METHODS

Authors screened the prices of antihypertensive drugs of different strength available in India from website medguideindia.com, CIMS (current index of medical specialities) Jan-Apr 2018, Drug Today (April-June 2018).⁵⁻⁷ Price list of antihypertensive drugs covered under the DPCO was downloaded from the government of India website <http://nppaindia.nic.in>. The study was done in the month of May 2018. Unit prices (per tablet/capsules/injection/other dosage forms) were expressed in Indian rupee (INR) of drug formulations and compared with DPCO price list 2017.

Inclusion and exclusion criteria

Only those drugs are included in the study which are enlisted in the DPCO list 2017. All of the included drugs were available orally. Authors also included sodium nitroprusside which was available as injection. Fixed dose combinations are also excluded.

Authors observed the total number of pharmaceutical companies preparing a particular formulation. Percentage of brands those were selling the drugs above and below the DPCO price list 2017 was calculated. Authors didn't compare the drugs price with latest DPCO list 2018 as it is recently released in April and pharmaceutical

companies and drug information books need some time (about forty-five days) to be updated.

Statistical methods

Data was entered in Microsoft excel 2010. Percentage of selling price above and below the DPCO price list was calculated for each drug.

RESULTS

In this study authors tried to find out the results of government efforts (NPPA/Department of Pharmaceuticals under Ministry of Chemicals and Fertilizer) to regulate cost of medicine.

Authors collected data of 30 formulations of 16 antihypertensive drugs. The total number of available brands of all formulations was 1365 out of which only 831 (60.88%) brands were found to have price less than DPCO recommended list. 534 (39.12%) brands had price more than the recommended limit (Figure 1).

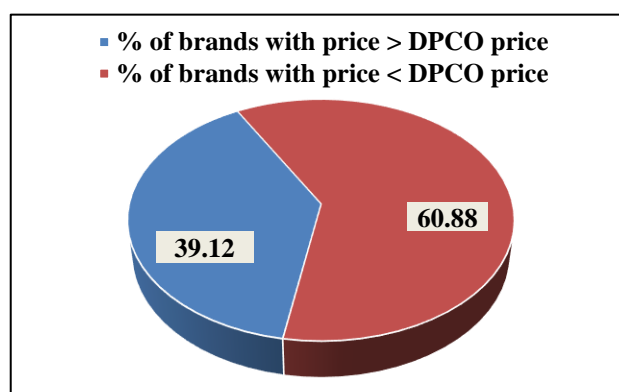


Figure 1: Drugs Price comparison as per DPCO 2017 illustrating the percentage of all scheduled formulations sold above and below the ceiling price list.

Amlodipine 5mg and telmisartan 40mg were found to have maximum number of manufacturers i.e., 182 and 126 respectively. The minimum violation of price limit was found in case of metoprolol 25mg i.e., only one (6.66%) out of 15 companies was selling at a price higher than DPCO ceiling price. At the same time maximum number of dosage forms (25mg, SR tab 25mg, 50mg, SR tab 50mg) were available for metoprolol (Table 1). 35.71% brands of amlodipine 5mg were selling it above DPCO price limit while 56.34% brands of telmisartan 40mg were available with price more than DPCO limit. (Figure 2).

Maximum price violation was observed with spironolactone 25mg and sodium nitroprusside inj 10mg/ml. Spironolactone was manufactured by only one and sodium nitroprusside by five pharmaceutical companies. All of them were selling these drugs above

the set price limit by DPCO. More than 50% brands of eight formulations (methyldopa 250mg, metoprolol SR tab 25mg, SR Tab 50, spironolactone 25mg, sodium

nitroprusside inj 10mg/ml, telmisartan 20mg, 40mg, 80mg) were selling their products above the recommended price (Table 1).

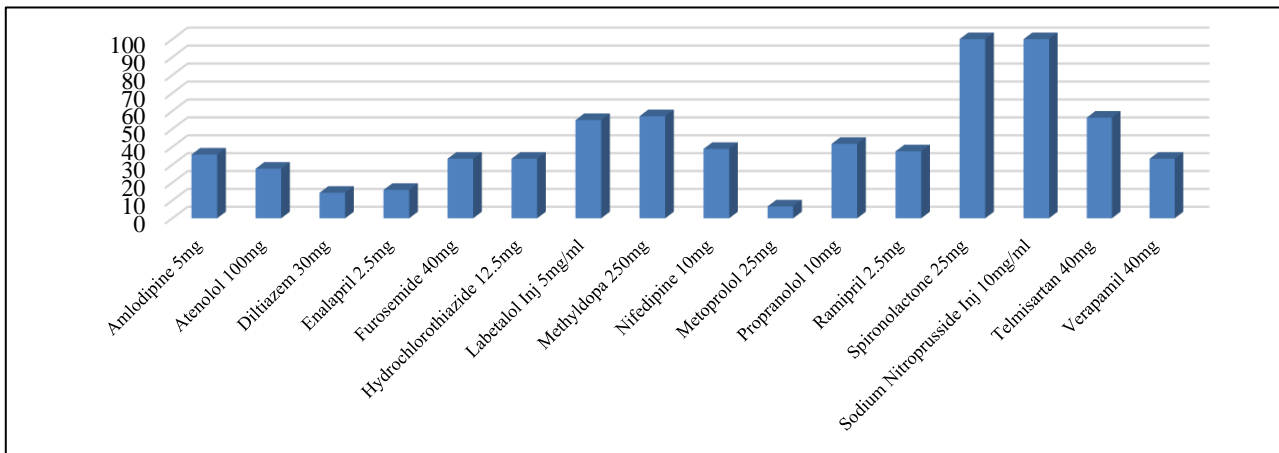


Figure 2: Percentage of antihypertensive drugs sold above the DPCO ceiling price list.

Table 1: Price comparison of antihypertensive formulations with DPCO list.

Drug	Dose and formulation	No. of brands	DPCO price (1 st April 2017)	No. of brands with price <DPCO price	No. of brands with price >DPCO price	% of brands with price >DPCO price
Amlodipine	10mg	69	4.80	53	16	23.18
	2.5mg	82	1.56	52	30	36.58
	5mg	182	2.38	117	65	35.71
Atenolol	100mg	54	3.30	39	15	27.77
	50mg	119	1.69	64	55	46.21
Diltiazem	30mg	42	2.27	36	6	14.28
	60mg	38	4.62	31	7	18.42
Enalapril	2.5mg	44	1.82	37	7	15.90
	5mg	55	3.03	49	6	10.90
Furosemide	40mg	3	.47	2	1	33.33
Hydrochlorothiazide	12.5mg	9	.93	6	3	33.33
	25mg	10	1.60	7	3	30
Labetalol	Inj 5mg/ml	20	47.96	9	11	55
Methyldopa	250mg	7	2.30	3	4	57.14
Metoprolol	10mg	18	1.17	11	7	38.88
	25mg	15	2.94	14	1	6.66
	SR Tab 25mg	65	3.82	30	35	53.85
	50mg	20	4.45	18	2	10
Propranolol	SR Tab 50mg	62	5.46	25	37	59.67
	10mg	24	1.09	14	10	41.66
Ramipril	40mg	31	2.61	23	8	25.80
	2.5mg	72	4.70	45	27	37.50
Spironolactone	5mg	77	7.42	48	29	37.66
	25mg	1	1.80	0	1	100
Sodium Nitroprusside	Inj 10mg/ml	5	24.42	0	5	100
Telmisartan	20mg	68	3.45	29	39	57.35
	40mg	126	6.24	55	71	56.34
	80mg	36	9.51	7	29	80.55
Verapamil	40mg	06	0.71	04	2	33.33
	80mg	05	1.31	03	2	40
Total		1365		831	534	

DISCUSSION

Maximum number of manufacturers were observed with amlodipine 5mg and telmisartan 40mg as these are most commonly prescribed and popular antihypertensive drugs.

The minimum violation of price limit was found in case of metoprolol 25mg and maximum price violation was observed with spironolactone 25mg and sodium nitroprusside inj. 10mg/ml.

Spironolactone is a potassium sparing diuretic which is mostly available in combination (as fixed dose combination) with other potassium lowering antihypertensive drugs like thiazides and loop diuretics. Spironolactone alone is manufactured by only one company and it may be the probable reason for selling it at a higher price.

Although sodium nitroprusside was manufactured by five companies, all of them were seen violating the price limit. This is not so popular antihypertensive drug due to many reasons like difficulty in storage, administration and requirement of dose titration.

In this previous study authors found a price variation of great extent among many antihypertensive formulations.⁸ Profit margin of pharmaceutical companies is extremely variable, often ranging from 1000% to 4000%.⁹ In 1995, the first Drug Price Control Order (DPCO-1995) was issued which included the prices of 76 drugs under the purview of price control.¹⁰ For the benefit of patients, government authorise NPPA to regulate prices of medicines which are included in the national list of essential medicines (NLEM) in 2013 i.e., 348 essential medicines. Government is making every effort for ensuring availability and affordability of medicines for all citizens of India. The order authorized the NPPA to regulate the medicine prices of not only NLEM but also medicines which are not listed in NLEM (non-NLEM).¹¹ But even after these efforts there is a great price variation and some drugs still cost more than the prescribed limits by DPCO. If any manufacturer sells a scheduled formulation at a price higher than the ceiling price fixed and notified by the government, such manufacturers shall be liable to deposit the overcharged amount along with interest thereon from the date of such overcharging.

On the other hand, government cannot be too stringent towards the pharmaceutical companies otherwise they may cease to manufacture such category of drugs which are under the regulation. Less profits hamper the pharmaceutical industry growth.¹²

In USA there is no strict price regulation and drug companies invest more on research and development due to more profit.¹³

But for the sake of society there must be some check and balance system. This is even more relevant in India as there is no well-defined social security system as well as medical insurance coverage is very poor and most of the health-related expenses are to be borne by the patients themselves. About 39 million Indians are becoming poorer every year due to rising health care costs and 30% patients die at home following discharge against medical advice from the intensive care units due to non-affordability of treatment.¹⁴

The FDA/ Drugs Control Organisation of the State is the enforcing agency of Drugs and Cosmetics Act and DPCO at state level. Therefore, all complaints on prices as well as quality of medicines can be lodged with the Drugs Inspector of the District or the State Drug Controller. Complaints regarding violation of prices can be lodged with NPPA directly also. Charging more than printed MRP of a medicine attracts the penal provisions of Drugs Price Control Order, 2013. Non-compliance of price notification issued by NPPA, depending upon the gravity of the offence, could attract prosecution under the section 7, 9 and 10 of Essential Commodities Act (ECA), 1955. Punishment for violating the DPCO order may be imprisonment from 3 months to seven years as well as financial recovery of overcharging amount along with interest as arrears to land revenue under the Public Demand Recovery Act.⁴

CONCLUSION

Large number of brands are not following the regulations and are violating the price limit set by NPPA/DPCO. Reassessment and monitoring for implementation of DPCO price list should be done to ensure the prices of drugs as per the DPCO price list. Implementation is the key factor to regulate the drug prices. Pricing of medicines is a very sensitive issue and it has direct economic implications on patients resulting into poor compliance to treatment. Our results clearly indicate that despite the measure of price control in India, many pharmaceutical industries are still selling the medicines above the recommended prices. The DPCO has not attained its objective completely to bring down prices of medicines. Government authorities need to revise their pricing policies and ensure regulatory checks to bring all brands prices within ceiling price limits. Beside price control it is also very necessary to monitor manufacturing of drug under GMP (good manufacturing practice) to ensure quality of medicine. It is the moral responsibility of all medical professional that cost effectiveness of drugs should be evaluated before prescribing it to any patients.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: Not required

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Cite this article as: Kumar R, Kumar N, Ahmad A, Kumar M, Rajendra N, Dixit RK, et al. Cost comparison of antihypertensive drugs available in India with Drugs Prices Control Order price list. *Int J Res Med Sci* 2019;7:101-5.