

**Original Article**

**COST ANALYSIS OF COMMONLY USED DRUGS UNDER PRICE CONTROL IN INDIA: ASSESSING THE EFFECT OF DRUG PRICE CONTROL ORDER ON BRAND PRICE VARIATION**

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**ABSTRACT**

**Objective:** Rising cost of medical therapy is a major concern for patients, and there is high variability in the prices of numerous branded medicines available in India. Drug Price Control Order (DPCO) 2013 was implemented by the government of India with the aim of bringing down the cost of essential medicines. This cost analysis study was carried out to assess the brand price variation in major classes of common drugs under price control; thus assessing the impact of DPCO and analyse issues related to it.

**Methods:** Latest price list of available brands for cardiovascular drugs, antibacterial, analgesics, drugs for diabetes, asthma, arthritis, convulsions covered under the DPCO, was procured from a leading commercial drug directory. Unit prices of drug formulations available as different brands were compared. Maximum-minimum prices and average prices were found. Price variations between brands were calculated and expressed as percentage variations. Assessment of existing pricing policy and quality norms was done.

**Results:** Significant inter-brand price variations were found for the majority of formulations. These variations ranged from more than 100 % from average to more than 500 % between maximum and minimum brand prices for drugs like amlodipine, atorvastatin, diclofenac, amoxicillin-clavulanic acid, clopidogrel. Out of 60 formulations observed, 40 showed price variations in excess of 50 % from average price and 23 showed variations greater than 200 % between the costliest and cheapest brands.

**Conclusion:** Despite the implementation of price control, brand price variations still exist widely for commonly used drugs. Re-assessment of pricing policy and implementation of quality norms is needed.

**Keywords:** Pharmacoeconomics, Price control, Brands, Price variation, Essential medicines

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**INTRODUCTION**

Pricing of medicines is a very sensitive issue for a developing country like India. It has direct economic implications on patients and plays a significant role in determining compliance to treatment; the plethora of brands available in India for the majority of drugs further complicates this problem [1]. To ensure that vital drugs are available at the affordable prices, the government of India exercises control over the prices of certain drugs defined as 'essential' through an order called Drugs (Prices Control) Order commonly referred to as the DPCO. The current DPCO became effective in May 2013 [2]. The National Pharmaceutical Pricing Authority (NPPA) implements this DPCO [3]. The National List of Essential Medicines (NLEM) is a list of medicines prepared by the Ministry of Health and Family Welfare, which satisfy the health care needs of the majority of the population [4].

Under the provisions of DPCO 2013, prices of the 348 drugs in NLEM 2011 are monitored and controlled by the NPPA [2]. Only 74 drugs were subjected to price control in the previous DPCO 1995 [5]. As per the compendium of ceiling prices published in 2015, effective from 1<sup>st</sup> April, the NPPA had fixed ceiling prices of 509 formulations out of a total of 628 net formulations to be covered under the DPCO. This has increased with subsequent notifications [3, 6-8]. "Ceiling price" means a price fixed by the government in accordance with the provisions of the DPCO [2].

This price control has come under scrutiny recently, with the Supreme Court of India calling the pricing policy as "unreasonable and irrational", and asking the government to re-examine it [9]. The DPCO had also come heavily under the scanner for bringing an additional 108 non-scheduled formulations under price control in the public interest, [10] then withdrawing its decision [11].

Multiple brands are available for a single drug in India and variations are known to be prevalent in the prices of these brands because an

open competitive market system entertaining both domestic and foreign manufacturers is followed [12]. With the implementation of price control, such price variations are expected to have come down. The DPCO states that reducing such inter-brand price variations in major therapeutic groups is one of its major aims [13].

'Cost analysis' is a type of partial pharmacoeconomic evaluation which compares the costs of two or more alternatives without regard to outcome [14, 15]. Different brands of the same drug are the alternatives available for a patient, expected to provide a same therapeutic outcome. Analysis of their costs can highlight the phenomenon of 'inter-brand price variation' which can put the substantial financial burden on patients along with posing moral and ethical concerns.

Few previously conducted studies have shown that there is indeed a wide variation in brand prices in the Indian market, but the data is still scant, and these studies focused on drugs in a single therapeutic area [16-18]. Assessing brand price variation of essential drugs under price control across multiple therapeutic areas would give a much better assessment of the actual state of price variations and the impact of current drug pricing policy.

Drugs for treatment of cardiovascular disorders like hypertension, heart failure, Myocardial Infarction (MI), bacterial infections including tuberculosis-leprosy, diabetes, asthma, epilepsy, arthritis, pain can be considered as some of the most commonly used drugs. Hence, these drug groups were chosen for cost analysis in this study.

**MATERIALS AND METHODS**

Current Index of Medical Specialities-CIMS (July–October 2015 edition, India) was referred to for dosage and prices of the different brands of the aforementioned groups of drugs. CIMS is considered a trusted and authentic source of commercial drug information and was chosen as the single source of information to ensure uniformity

of price data, and avoid repetition and ambiguity which may arise from using multiple sources. The average price was calculated by adding up the prices of different brands for a particular drug and dividing the sum by a total number of brands. Price variation calculations for drug formulations having a minimum of five available brands were included in the final observation as it was deemed unjustified to comment on price variations with less than five brands. The (single) unit prices for all oral formulations and injections were taken, as the DPCO also fixes ceiling prices for one unit. Special formulations like extended release/dispersible tab/controlled release etc. were excluded. The ceiling prices that have been notified in the compendium of notified ceiling prices 2015 were noted.

Following parameters were noted/calculated:

1. Retail unit prices of the different brands of the same drug formulations.
2. A number of brands available for a drug formulation.
3. The average price of each formulation.
4. Maximum and minimum prices for each formulation.
5. Percentage deviation of maximum and minimum prices from the average price: [17]

$$a) \frac{\text{Average price} - \text{Minimum price}}{\text{Average price}} \times 100$$

$$b) \frac{\text{Maximum price} - \text{Average price}}{\text{Average price}} \times 100$$

6. Percentage variation between maximum and minimum prices: [15]

$$\frac{\text{Price of the most expensive brand (max.)} - \text{Price of the least expensive brand (min.)}}{\text{Price of the least expensive brand (min.)}} \times 100$$

## RESULTS

Out of the 27 therapeutic areas in the NLEM brought under price control through DPCO 2013, we looked up the brands and prices available for drugs from six therapeutic areas (Cardiovascular drugs, anti bacterial, analgesics-anti-inflammatories, antidiabetic, antiasthma, anticonvulsants, anti-arthritis drugs) in CIMS. We could find 36 drugs and their 60 different dose formulations from the above categories of drugs. Among the drugs used for *cardiovascular diseases* [table 1], we observed 10 drugs in 17 formulations. All formulations, except three, showed more than 100 % variation between maximum and minimum priced brands. Five formulations showed more than 500 % variation; largest with Clopidogrel 75 mg tablet (1067.5 %) followed by amlodipine 5 mg tab (1040.48 %). These drugs also showed the highest variation of maximum price from average price (278 and 227.87 % respectively). The relatively cheapest brand (largest variation of minimum price from average) was Atorvastatin 10 mg tab-also having the highest numbers of 58 brands listed.

**Table 1: Brand-Price variation in cardiovascular drug formulations under DPCO**

Drug	Dose and formulation	No. of brands	Avg. price (Rs.)	Maximum price (Brand)	% var. from avg.	Minimum price (Brand)	% var. from avg.	% var. between max. and min.	DPCO ceiling price
Atenolol	50 mg Tab	22	2.10	3.792	80.57	0.57	72.85	565.3	2.28
	100 mg Tab	9	3.537	Tenormine 5.478	54.88	2.571	27.31	113.1	4.11
Metoprolol	25 mg Tab	9	2.781	Tenormine 3.77	35.56	1.2	56.85	214.17	3.73
	50 mg Tab	7	4.31	Metzok 5.597	28.86	1.85	57.08	202.54	5.54
Enalapril	2.5 mg Tab	11	1.602	Metzok 2.26	41.07	0.88	45.07	156.82	1.96
	5 mg Tab	12	2.594	Envas 3.684	42	1.5	42.17	145.6	3.27
Amlodipine	2.5 mg Tab	25	1.614	Enace 4.4	172.6	0.57	64.68	671.93	1.97
	5 mg Tab	34	2.623	Amlogard 8.6	227.87	0.754	71.25	1040.58	3.13
Losartan	25 mg Tab	31	2.623	Amlogard 4.51	71.94	1.2	54.25	275.83	2.76
	50 mg Tab	34	4.784	Losacar 9.38	96.07	2.45	48.79	282.86	4.75
Atorvastatin	5 mg Tab	20	3.44	Losacar 6.89	100.29	0.9	73.84	665.55	4.22
	10 mg Tab	58	5.66	Storvas 10.45	84.63	1.2	78.8	770.83	6.74
Streptokinase	1500000 IU Inj	5	2868.2	Atorva 3393.92	18.33	2300	19.81	47.56	2245.83
Clopidogrel	75 mg Tab	21	5.58	Icikinase 13.94	278	1.194	78.6	1067.5	11.07
Isosorbide mononitrate	10 mg Tab	6	1.714	Stromix 2.244	31	1.26	26.45	78.1	2.12
	20 mg Tab	9	2.675	ISMO 3.721	39	1.467	45.16	153.65	3.63
Diltiazem	30 mg Tab	5	1.82	ISMO 2.27	24.73	Solotrate 1.475	18.96	53.9	2.5
				Dilticard		Dilcal			

Abbreviations: avg. = average, var. = variation, max. = maximum, min. = minimum

We observed 15 drugs in 28 formulations among the *antibacterials* [table 2, 3]. 24 formulations showed more than a 100 % price variation between maximum and minimum priced brands. Largest variation was shown by ethambutol 400 mg tab (480.28 %) followed by cefixime 200 mg tab (389.9 %). The

highest variations from average price were shown by amoxicillin+clavulanic acid 625 mg tab and ethambutol 400 mg tab (111.7 % and 98 % respectively). The former also had maximum 90 brands available, followed by azithromycin 500 mg injection with 83 brands.

Table 2: Brand-Price variation in beta-lactam antibacterial drug formulations under DPCO

Drug	Dose and formulation	No. of Brands	Avg. price (Rs.)	Max. price (Brand)	% var. from avg.	Min. price (Brand)	% var. from avg.	% var. between max. and min.	DPCO ceiling price
Amoxicillin	250 mg Cap	24	3.62	6.9 Wymox	90.5	2.678 Cidomex	26	157.65	3.04
	500 mg Cap	29	6.648	11.3 Wymox	69.9	5.3 Ranoxyl	20.2	113.2	6.72
Ampicillin	250 mg Cap	7	3.102	4.63 Ampilin	49.2	1.74 albercilin	43.9	166.09	2.76
	500 mg Cap	5	5.806	8.95 Ampilin	54.1	3.24 albercilin	44.1	176.23	5.24
	500 mg Inj	5	9.926	15 Ampicillin	51.1	4.24 ampijet	57.2	253.77	14.8
Cefotaxime	250 mg Inj	11	18.46	27.69 Claforan	50	12.92 Sifotaxim	30	114.31	15.77
	500 mg Inj	9	27.15	42.94 Spinocef	58.1	17.31 Sifotaxim	36.2	148.06	20.82
Ceftazidime	1 g inj	10	296.7	457 Fortum ES	54	222.9 Izid	29.4	105.02	253.05
Ceftriaxone	250 mg inj	39	29.58	49 Cetazone	65.6	21.38 Cetriax	27.7	129.18	27.16
	1 g inj	51	69.9	125.4 Cetazone	79.3	46.95 Mahacef	32.8	167.09	61.21
Cephalexin	250 mg Cap	6	6.48	8.9 Sporidex	37.3	4.762 Neocef	26.5	86.89	5.79
	500 mg cap	9	12.85	16.995 Phexin	32.2	8.872 Neocef	30.9	91.55	12.87
Amoxicillin clavulanic acid	625 mg Tab	90	22.43	47.5 Klamentin	111.7	9.9 Clovista	56	379.79	24.80
	1.2 g inj	39	147.6	214.4 Augmentin	45.2	59 Pheoclave forte	60	263.38	140.63
Cefixime	100 mg Tab	27	8.21	11 Taxim O	33.98	4 Raxim	51.28	175	8.49
	200 mg Tab	57	12.88	24.25 Letix	88.28	4.95 Mahacef	61.57	389.9	12.42

Table 3: Brand-Price variation in antibacterial drug formulations (other than beta-lactam) under DPCO

Drug	Dose and formulation	No. of Brands	Avg. price (Rs.)	Max. price (Brand)	% var. from avg.	Min. price (Brand)	% var. from avg.	% var. between max. and min.	DPCO ceiling price
Vancomycin	500 mg Inj	7	336.5	389 Vancover	15.6	250 Vancorin	25.7	55.6	365.02
Amikacin	250 mg/2 ml Inj	19	18.24	31.5 Ivimicin	72.6	14.5 Kyocin	20.5	117.24	15.41
	100 mg Tab	5	6.51	7.4 Yanic	13.6	4.99 Azi-Big	23.3	48.3	5.66
Azithromycin	250 mg Tab	70	11.55	17.95 Azitrac	55	6.5 Azostar	43.7	176.15	11.33
	500 mg Inj	83	22.24	35.93 Aziwok	61	13.97 Zady	37	157.19	22.65
	250 mg Tab	29	3.52	5.98 Cifran	69.8	2.545 Zoxan	27.6	134.97	2.1
Ciprofloxacin	500 mg Tab	35	6.37	11.228 C-OD	76.2	4.1 Alcip	35.6	173.85	4.01
	200 mg/100 ml Inj	6	0.31	0.51 Cifran	63	0.17 Ciprobid	43.2	200	0.27
	400 mg Tab	5	2.08	4.12 Mycobutol	98	0.71 Albutol	65.8	480.28	2.4
Ethambutol	800 mg Tab	6	3.45	4.45 Mycobutol	28.9	1.36 Albutol	60.5	227.2	4.13
	450 mg Cap	5	5.8	6.89 Zucox	18.7	4.8 Rimactane	1	43.54	4.22
Gentamicin	40 mg/ml Inj	5	7.546	8.02 Garamycin	6.28	7.21 Genticyn	4.45	11.23	2.41

Among the drug formulations for *analgesia-inflammation, asthma, diabetes, arthritis* (table-4), 15 drug formulations were observed. Seven of these showed more than a 200 % price variation between maximum and minimum priced brands. The largest variation was

seen with diclofenac 25 mg/ml injection (2060.8 %) which also showed maximum variation from average price (356.7 %). The relatively cheapest brand was paracetamol 500 mg tab (113.2 %). Diclofenac 25 mg/ml injection had the maximum brands listed (22).

Table 4: Brand-Price variation in miscellaneous drug formulations under DPCO

Drug	Dose and formulation	No. of Brands	Avg. price (Rs.)	Max. price (Brand)	% var. from avg.	Min. price (Brand)	% var. from avg.	% var. between max. & min.	DPCO ceiling price
Insulin	40 IU/ml Inj	5	141.17	145.66 Insugen-N	3.1	129.24 Lentard-40	8	12.7	
Metformin	500 mg Tab	17	1.269	2.0 Metford	57.6	0.645 Forminal	49.1	210.07	1.72
Diclofenac	50 mg Tab	16	1.426	2.46 Diclonova	72.5	0.61 Jonac	57.2	303.27	2.15
	25 mg/ml Inj	22	5.66	24.85 Dicloran	356.7	1.15 OxalginD	76	2060.8	1.64
Paracetamol	500 mg Tab	19	1.073	1.6 Pacipik	49.1	0.488 Doliprane	113.2	227.86	1.04
Tramadol	50 mg Cap	6	7.47	9.15 Tramazac	22.48	6.3 Relidol	15.66	45.23	6.66
	50 mg/ml Inj	11	13.54	18.9 Tramazac	39.5	7.15 Stemadol	47.1	164.33	12.95
Allopurinol	100 mg Tab	6	2.5	3.74 Zyloric	49.6	1.45 Lodiric	42	157.93	2.31
Leflunomide	10 mg Tab	6	9.923	13 Feluno	31	8 Lisifen	19.3	62.5	16.67
	20 mg Tab	5	18.9	23.44 Cleft	24	16 Lisifen	15.2	46.5	31.61
Hydroxy-chloroquine	200 mg Tab	5	5.55	6.99 MCQs	25.9	4.83 ZY-Q	38.7	44.72	6.23
Salbutamol	2 mg Tab	5	0.214	0.328 Asthalin	53.2	0.1 Salbid	53.2	228	0.16
	4 mg Tab	5	0.357	0.59 Asthalin S	65.2	0.164 Salbid	54	259.75	0.19
Dexamethasone	0.5 mg Tab	6	0.224	0.27 Dexona	20.53	0.21 Demisone	6.25	28.57	0.21

We also found that a number of the highest priced brands had prices above the fixed ceiling prices, substantially so in some cases.

## DISCUSSION

The results clearly indicate that despite the measure of price control in India, significant inter-brand price variations still exist in the pharmaceutical market. The DPCO was expected to bring down or even eliminate such inter-brand price variations, but it has not achieved its objective completely. Huge inter-brand price differences in the marketing of branded generics are indicative of a severe market failure, as recognized by the NPPA itself [18].

### Magnitude and significance of price variation

Such large brand price variation in the 'price controlled' essential drugs is alarming, with prices of the most expensive brands being upwards of 100–200 % from average for many commonly used drugs. In some cases, the costliest brands are more than 1000 % expensive than the cheapest brands. These variations are comparable to the brand price variations in previous studies [16-17] conducted before the DPCO came to effect in 2013. This means that current price control mechanisms haven't been successful in bringing down the brand price variations effectively. An expensive brand can cost a patient more than 10 times a cheaper brand and 2 times the average price. It is a grave state in the context of India where health insurance is still an alien concept, and 50-90 % of the medicine cost is borne by the patient [19-21].

The consequences of this unwarranted expenditure become more severe in the management of chronic diseases like hypertension, dyslipidaemia, arthritis, tuberculosis, diabetes. The brand price differences can run into huge numbers with therapy required for years or even lifetime. For example, the highest consumption of antibiotics in the world is seen in India (13 billion standard units per year) [22], the average cost of monthly single drug therapy for hypertension is estimated to be 1.8 times the day's wages (average) with every 3<sup>rd</sup> individual over 18 now supposedly having hypertension [23-24], the average direct annual costs per diabetic patient is around Rs. 15000 and rises up to four times with complications [25] whereas the same has been found to be up to

\$598 for asthma [26]. Clearly, these illnesses create a substantial financial burden and can result in a compromise on diagnosis and treatment with affordability suffering further with polypharmacy.

It is also difficult to understand how some brand prices are still above ceiling prices. Could this be due to non update or revision of prices by companies or due to the addition of local taxes? We noted ceiling prices which became effective from 1<sup>st</sup> April 2015 [3, 27]. The CIMS prices are from July onwards, so the 45 d grace period provided in the DPCO for revision of prices had passed. This poses a question mark on the measures being taken by the government for active surveillance to implement price control.

### Possible reasons for price variations

One of the primary reasons for brand price variation in Indian pharmaceutical market is the very nature and composition of pharma sector in India which is predominantly a branded generic market i.e. multiple companies sell a particular drug under different brand names. Hence, the number of brands available in the market is very high: 60,000-70,000 [28]. Similarly, factors like the asymmetry of information or imperfect information, government regulations and pricing policies, costs of raw supplies, distribution and promotion, economic goals of the parent company, target return on investment also contribute to this phenomenon [29-32].

Doctors usually end up prescribing more widely endorsed and meticulously marketed brands to the patients not keeping in mind the cost of the drug. Patients may be non-compliant to the costly brands or reduce doses taken in order to save money. A sizable part of the company's marketing including the continuing medical education activities (CMEs), is spent on inappropriately persuading doctors to prescribe their drugs [33]. Pharmacists also dispense the most expensive brands for higher profit margin. They may also have tie up with particular companies, selectively stocking only their products.

### Price variations in context of the current pricing policy

The DPCO is a welcome initiative by the government aimed at checking the rising drug prices. But there seems to be a fault in the

design and implementation of the order. The pricing policy needs to be scrutinised, as rightly pointed out by the honourable Supreme Court, [8] taking cognizance of the fact that generic drugs are being made available by governments of Kerala, Tamil Nadu at costs up to 4000 % lesser than the ceiling prices!

The current pricing policy is a *market based policy* whereby ceiling prices are determined by simply averaging the prices of brands of all companies which have a market share greater than 1 %, plus an additional margin of 16 % to the retailer [3]. There is also the provision of extra addition of local taxes to this cost. So, in effect, the ceiling prices are actually influenced by the already existing prices of popular brands in the market. A much better alternative would be adopting the *cost of manufacture* based formula used in the old pricing policy (DPCO 1995). It stated that the retail price of a formulation shall be calculated by the Government in accordance with the following formula namely: [34]

$$R. P. = (M. C. + C. C. + P. M. + P. C.) \times (1 + MAPE/100) + ED.$$

where M. C. means material cost, C. C. means conversion cost, P. M. means the cost of the packing material, P. C. means packing charges; MAPE means Maximum Allowable Post-manufacturing Expenses; ED means excise duty.

As is evident, in this formula the material cost, conversion cost, cost of packing material/charges, post-manufacturing expenses, excise duty were all taken into account to determine ceiling prices. It would be highly recommended to use this formula for an improved pricing policy; whereby the government finds out what is the actual cost of manufacture of a particular drug and then provides a reasonable margin to the manufacturer/retailer over it. It might bring down the ceiling prices sufficiently to disallow the unfairly high pricing of brands. Currently, it seems that ceiling prices themselves are too high which is contributing to the extensive brand price variation.

#### Varying brand prices-Is it an issue of quality?

Questions are often raised regarding the quality of the so called cheaper brands. Ideally, all drug manufacturers have to follow the Good Manufacturing Practices (GMP) norms laid out in the schedule M of the Drugs & Cosmetics Act 1945. GMP covers all aspects of production quality and standards-raw materials, premises, equipment, training and personal hygiene of the staff and involves a stringent verification process before the issue of a GMP certificate to a drug manufacturer [35].

But the reality seems to be different. As noted in a recent review, probably 12-25 % of the medicines supplied globally from India is contaminated, substandard and counterfeit [36]. As per World Health Organization, poor quality drugs are the spurious/falsely-labelled/falsified/counterfeit (SFFC) drugs that can cause treatment failure or even death [37] and 75 % of the global cases of SFFC medicines originate from India [38]. The Central Drugs Standard Control Organization (CDSCO) has categorised such drugs as not of standard quality (NSQ) products. A recent study, aiming to know the correct extent of the SFFC or NSQ drugs in India, found that quality control mechanisms in place for manufacture and sale drugs in India are not good enough. While official data from several studies suggested presence of 3-12 % drugs of spurious and/or substandard quality drugs, data from Indian media suggests this to be in the region of 30-40 % [39]. Recently, Indian generics of reputed companies have also come under US Food and Drug Administration (FDA) scanner for quality related issues due to violations in manufacturing processes [40].

This suggests an absence of stringent enforcement of the rules and regulations or possible corrupt practices in local FDAs. There is a reported shortage of drug inspectors for regular vigilance over manufacturing units and distribution outlets [41]. The incidence of death of numerous women is reportedly consuming ciprofloxacin tablets mixed with zinc phosphide—a rat poison, in Raipur, Chhattisgarh shows there are serious issues related to adherence to drug manufacturing standards by small-scale manufacturers [42].

Technically, all brands need to be bioequivalent which means their plasma level profiles should be comparable and super imposable

within prescribed limits (80-125 %) [43]. This bioequivalence may differ significantly due to inadequate BE studies by smaller firms. In the case of drugs like phenytoin, warfarin, digoxin that show a steep dose response curve, even a slight difference in bioavailability of different brands can cause serious adverse effects. Similarly, drugs having a narrow margin of safety like antiarrhythmics, theophylline, and adrenal steroids may be affected too [43]. The inadequate bioequivalence may also translate into a loss of therapeutic effectiveness.

Thus the question of 'branded generics', available as so-called cheaper alternatives to the strictly branded drugs (which are actual innovator products) becomes a sensitive issue to address. In India, almost all medicines in India are sold under a brand/trade name and may be *branded* medicines or *branded-generic* (simply called generics worldwide). Actually, there are very few *branded* medicines in the Indian market as till January 2005 product patent was not applicable in India; most drugs are in fact generics with a brand name! Many pharmaceutical companies manufacture two types of products for the same molecule, i.e. the *branded* product which they advertise and push through doctors and *branded-generic* which are expected to be pushed by retailers. The so-called *branded* medicines are manufactured and promoted by reputed multinationals or Indian manufacturers. Although the generic medicines are bio-equivalents of their innovator counterparts, these are widely believed as inferior in their therapeutic efficacy and quality to *branded* products. A study comparing these two versions of drugs has indicated that both the *branded* and *branded-generic* versions of the medicines had identical quality, and they fulfilled all the criteria prescribed by the statutory standards [44].

Some studies have revealed *retailer margins for the branded generics are very large (200-1000 %) compared to branded drugs (25-30 %)*. Pharmaceutical companies decide the final price (MRP) to the patient as well as the margins for the retailer. If the marketing and promotion are done by the retailer as in the case of *branded-generic* then the Price To Retailer is less, but MRP is not much different. Therefore, the ultimate consumer, i.e. patient is not benefited much by preferring *branded-generic* versions to its *branded* version. The huge profit margins for retailers ranging from 500 % to 1000 % on generic medicines in India have been reported [45].

Use of good quality generic drugs, which are bioequivalent to brand name drug, can help contain prescription drug spending. The government of India has opened few generic drug stores in some states that sell generic medicines manufactured by public sector companies [46]. The quality of generic medicines available on these stores at cheaper rates should be tested and compared with popular brands, and results should be widely published.

Suitable changes in the drug price policy may be made to have lower prices for *branded-generic* versions. Transparency in fixing the MRP by the manufacturer and clear guidelines for markups at least for *branded-generics* is also recommended.

#### Scope of DPCO—need for improvement

Firstly, the NLEM needs to be revised, to allow inclusion of a wider spectrum of drugs in the DPCO. Many newer and commonly used drugs in a current scenario like anticancer, antimicrobial, antidiabetic, organ transplantation drugs need to be included in the NLEM [47]. More drug combinations need to be covered in the NLEM, as they account for almost 45 % of the total pharma market [48]. A number of pharma companies have also started circumventing the provisions of DPCO by changing the composition and strength of formulations to evade price control as well as introducing the 'me too' drugs which are similar to each other in structure and offer an only marginal advantage over existing treatment [49]. This practice needs to be curbed. The government should also use its special authority to cap the prices of non-scheduled drugs (not in the NLEM), by citing them to be in the public interest [18]. In accordance with this provision, the NPPA had ordered capping of prices of 108 non-essential drugs in July 2014, including important cardiovascular and antidiabetic medicines [10-11]. But there was intense industry opposition to this move from the industry [50]. The government subsequently withdrew the earlier

guidelines in September 2014, essentially ending the NPPA's power to bring non-scheduled formulations under price control [51]. With the implementation of DPCO, only 13 % of the total Indian pharmaceutical market has actually come under price control out. So the brand price variation in the non-price controlled market can be deemed to be even bigger.

Another suggestion to check high pricing of drugs could be the provision of incentives to drug manufacturers through other means like tax benefits (similar to orphan drugs).

#### Expanding health insurance

A different approach could be introducing a comprehensive health insurance system, with the government purchasing bulk volume of drugs from manufacturers to ensure that industry also receives its fair profit margin akin to the systems employed by the U. S. and U. K. [52]. Studies have also shown that providing a manual of comparative drug prices annotated with prescribing advice to physicians reduced their patient's drug expense [53].

#### CONCLUSION

Given the magnitude of inter-brand price variations observed among the drugs under price control and the detrimental impact it has on patient's financial resources, we strongly recommend that the government authorities need to revise their pricing policies and ensure regulatory checks to bring all brand prices within ceiling prices. There is ample scope for significant reduction in NPPA ceiling prices. There should be an expansion of the list of essential medicines. There should be strict adherence to the GMP norms in drug manufacture. There is a moral obligation at the level of healthcare professionals too, especially physicians, to keep drug prices in mind while prescribing drugs to patients. On a positive note, more drugs have been notified for price control recently, and there has been a decline in a number of poor quality drugs cases. But it is imperative that this matter be considered and monitored vigorously to safeguard the interests of the patient community.

#### CONFLICTS OF INTERESTS

All authors have none to declare

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#### CONFLICT OF INTERESTS

Declare none

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