Research Article

Cost variation study of different brands of psychiatric drugs available in Indian market with reference to Indian Drug Price Control order

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ABSTRACT

Background: Cost of medicine is a governing factor of health-care system. It is the responsibility of the government to ensure the availability of essential medicines at an affordable price to all sections of the society. With an aim to improve the availability of essential medicines at affordable cost, the Ministry of Pharmaceutical, Chemicals, and Fertilizers implemented the drug price control order (DPCO) 2013. As per Global Burden of Disease report, mental disorders account for 13% of total disability-adjusted life years lost for years lived with disability. We conducted this study with the aim to analyze percent cost variation of different psychiatric disorders medicine brands available in Indian market with reference to DPCO. **Objective:** The objective of this study was to calculate percent cost variation of different brands of commonly used psychiatric disorder drugs available in Indian market with reference to DPCO, India. **Materials and Methods:** Information regarding cost of different brands of these medicines available in Indian market was taken from latest edition of Current Index for Medical Specialties. Percent cost variation between DPCO price and least costly brand as well as most expensive brand of individual medicine of selected strength was calculated and compared. **Results:** A total of 18 commonly used psychiatric disorder medicines were included in this study. Percent cost variation between DPCO price and least expensive brand available in Indian market was found maximum (–69.4586) for risperidone and minimum (0.6711) for phenytoin 100 mg capsules. Percent cost variation between DPCO price and most expensive brand available in Indian market was found maximum (812.6246) for risperidone 1 mg tablet and minimum (zero) for clozapine 50 mg tablet. **Conclusions:** In our study, we found that for most of the formulations, DPCO price was higher than least expensive brand available in Indian market. Indian government needs to revise drug pricing policy to bring all brands prices within ceiling price limits to achieve goal of universal health coverage.

KEY WORDS: Drug Price Control Order; National List of Essential Medicine; Out-of-Pocket Expenditure; National Pharmaceutical Price Authority

INTRODUCTION

In India, health department is one of the important sectors from the perspective of revenue and employment. Health-care organizations and pharmaceuticals constitute approximately 65% of the overall market come under health-care delivery.[1] The current worth of Indian health-care market is US$ 100 billion which anticipated to grow to US$ 280 billion by 2020.[2] Indian pharmaceutical market is a fast-growing pharmaceutical market in the globe. In 2017, the value of Indian pharmaceutical sector was US$ 33 billion which is expected to reach US$ 55 billion by 2020.[3] In Indian pharmaceutical sector, generic drugs have 70% of market share in terms of revenue and of total market revenues of US$ 20 billion, over-the-counter medicines, and patented drugs comprise 21% and 9%, respectively (IBEF, 2016).[4]

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Moreover, cost of production of pharmaceutical sector in India is considerably lesser than that of the US and almost half of that of Europe (IBEF, 2016).[5]

India is one of the developing countries. Around 42% of population of this country lives under the national poverty line ($1.25 per day). Medicine is a part of health-care cost and it costs to around 70–80% of total cost. Vital issue concerning them is to access the health-care facility at an affordable cost. Cost of medicine is a governing factor of health-care system.[6] Statistical data show that government is expending money in health-care facilities, approximately 10% of which is spent on medication expenses.[6,7] It is the responsibility of the government to ensure the availability of essential medicines at an affordable price to all sections of the society. Pharmaceutical companies in India have to formulate strategy according to the policy of Indian government.[2]

With an aim to improve the availability of basic health care and essential medicines at affordable cost, the Ministry of Pharmaceutical, Chemicals, and Fertilizers implemented the drug price control order (DPCO) 2013 ("DPCO 2013") in May 2013, which fixed prices 348 essential medicines. In 1995, the order included 74 bulk drugs and the drugs were priced based on the cost announced by the pharmaceutical manufacturers. In 2013, National Pharmaceutical Pricing Authority (NPPA) took charge as a regulatory authority to fix the prices of 348 essential medicines under DPCO order. DPCO 2013 included all medicines which are listed in National List of Essential Medicine (NLEM). DPCO was implemented with the objective of reducing the cost of medicines required by the government. The price list of essential medicines is released every year by the NPPA to guide pharmaceutical companies to control the prices of medicines in India.[8] NPPA follows National Drug Pricing Policy to monitor and control drug price and uses market-based pricing approach to fix drug price. Violation of DPCO may cause the manufacturer to get a notice period of 45 days, within which the drug price revision must be made and the amount overcharged along with interest and the penalty will have to be submitted to the government.[1,9]

As per Global Burden of Disease report, mental disorders account for 13% of total disability-adjusted life years lost for years lived with disability with depression being the leading cause.[10] Previous reviews, meta-analysis, studies, and independent reports have indicated that nearly 100 million persons in India are in need of systematic care based on data that are a few decades old and have serious methodological limitations. According to NMHS report, 10.6% of the population met the criteria for any mental morbidity. Schizophrenia and other psychotic disorder prevalence are 1.4%**.** The prevalence of epilepsy was 0.3%, with nearly 2 million persons requiring care.[11,12]

To the best of our knowledge, there is no study that has compared the cost variations of branded psychiatric disorders medicines with DPCO price. We conducted this study with the aim to analyze percent cost variation of different psychiatric disorders medicine brands available in Indian market with reference to DPCO.

MATERIALS AND METHODS

This study does not required ethical approval as this study involves only analysis of data which are freely available in public domain. The complete list of psychiatric medicines included in NLEM 2015, India was prepared. Information regarding cost of different brands of these medicines available in Indian market was taken from latest edition of current index for medical specialties. Percent cost variation between DPCO price and least costly brand as well as most expensive brand of individual medicine of selected strength was compared. Only those formulations which have two or more brands were included in this study. During percent cost variation, we hypothesized that DPCO price is lesser than least costly band available in India; therefore, if value of percent cost variation comes in minus, it indicates that DPCO price is higher than least costly brand.

RESULTS

DPCO price of psychiatric disorder drugs was compared with the price of least expensive and most expensive brand of formulation available in Indian market. We included total 18 commonly used psychiatric disorder medicine in this study. Number of brands available in Indian market were maximum, that is, 18 for escitalopram. We found wide cost variation between DPCO price and branded price when compared. Our study found that for 15 formulations, DPCO price was higher than respective least expensive brand available in Indian market. Percent cost variation between DPCO price and least expensive brand available in Indian market was found maximum (–69.4586) for risperidone and minimum (0.6711) for phenytoin 100 mg capsules. On calculation of percent cost variation between DPCO price and most expensive brand available in Indian market, we found maximum percent cost variation (812.6246) for risperidone 1 mg tablet and minimum (zero) for clozapine 50 mg tablet. For amitriptyline, maximum percent cost variation with least costly brand and most costly brand were found for 50 mg tablet (–65.669) and 10 mg tablet (25.00), respectively. For carbamazepine, maximum percent cost variation with least costly brand and most costly brand were found for 100 mg tablet (5.970149) and 100 mg tablet (823.8806), respectively. For clobazam, maximum percent cost variation with least costly brand and most costly brand were found for 5 mg tablet (–30.4175) and 10 mg tablet (33.71041), respectively. For clozapine, maximum percent cost variation with least costly brand was found for 25 tablets (–26.4228) and with most costly brand was found for 100 mg tablet (3.562005). For clonazepam, both maximum percent cost variation with

Table 1: Percent cost variation between different psychiatric medicine brands available in Indian market with DPCO price

Name of medicine	Dosage form and strength	DPCO price/unit (in INR)	No. of brands available in India	Least costly brand price/ Unit (in INR)	Most expensive brand price/ Unit (in INR)	% cost variation from least costly brand (in INR)	% cost variation from most expensive brand (in INR)
Amitriptyline	Tablet 10 mg	2.24	13	1.1	2.8	–50.8929	25.00
	Tablet 25 mg	2.21	16	1.5	2.38	–32.1267	7.692308
	Tablet 50 mg	5.68	7	1.95	6.10	–65.669	7.394366
	Tablet 75 mg	5.49	9	3.10	6.47	–43.5337	17.85064
Carbamazepine	Tablet 100 mg	0.67	2	0.71	6.19	5.970149	823.8806
	Tablet 200 mg	1.36	5	1.30	1.63	–4.41176	19.85294
Clobazam	Tablet 10 mg	8.84	9	6.50	11.82	–26.4706	33.71041
	Tablet 5 mg	5.03	7	3.50	6.24	–30.4175	24.05567
Clozapine	Tablet 100 mg	7.58	7	6.00	7.85	–20.8443	3.562005
	Tablet 25 mg	2.46	6	1.81	2.50	–26.4228	1.626016
	Tablet 50 mg	4.70	4	4.50	4.70	–4.25532	0
Clonazepam	Tablet 0.25 mg	1.79	8	1	2.20	–44.1341	22.90503
	Tablet 1 mg	4.14	10	3.20	4.30	–22.7053	3.864734
Diazepam	Tablet 2 mg	1.47	2	0.50	1.70	–65.9864	15.64626
	Tablet 5 mg	1.39	5	0.73	2.00	–47.482	43.88489
Donepezil	Tablet 10 mg	15.70	2	16.27	17.10	3.630573	8.917197
Escitalopram	Tablet 10 mg	7.93	18	3.00	8.73	–62.169	10.08827
	Tablet 20 mg	12.52	10	7.50	14.20	–40.0958	13.41853
	Tablet 5 mg	4.47	11	2.38	4.80	–46.7562	7.38255
Flunarizine	Tablet 10 mg	4.63	14	2.80	5.49	–39.5248	18.57451
	Tablet 5 mg	2.70	13	1.38	2.98	–48.8889	10.37037
Fluoxetine	Capsule 10 mg	2.91	2	1.50	3.12	–48.45	7.2164
	Capsule 20 mg	3.57	7	2.70	3.86	–24.36	8.1232
	Capsule 60 mg	9.58	5	5.90	10.28	–38.41	7.306
	Tablet 10 mg	2.44	2	2.40	2.57	–1.63	5.327
	Tablet 20 mg	3.88	3	3.00	6.50	–22.68	67.525
Haloperidol	Tablet 1.5 mg	1.62	7	0.66	1.70	–59.2593	4.938272
	Tablet 10 mg	4.32	7	2.25	4.80	–47.9167	11.11111
	Tablet 20 mg	4.82	2	4.57	4.59	–5.18672	–4.77178
	Tablet 5 mg	3.37	9	1.26	3.61	–62.6113	7.121662
Lithium	Tablet 300 mg	1.43	3	1.32	2.60	–7.69231	81.81818
Lorazepam	Tablet 1 mg	2.02	11	1.20	2.13	–40.5941	5.445545
	Tablet 2 mg	2.46	11	1.51	2.60	–38.6179	5.691057
Levetiracetam	Tablet 250 mg	5.72	3	5.70	6.14	–0.34965	7.342657
	Tablet 500 mg	11.57	5	11.91	12.43	2.938634	7.433016
	Tablet 750 mg	17.79	3	15.90	74.80	–10.6239	320.4609
Phenytoin	Capsule 100 mg	1.49	3	1.50	1.63	0.671141	9.395973
	ER Capsule 300 mg	3.73	2	5.26	6.10	41.01877	63.53887
Risperidone	Tablet 1 mg	3.01	8	0.81	27.47	–73.0897	812.6246
	Tablet 2 mg	4.82	7	1.68	5.14	–65.1452	6.639004
	Tablet 4 mg	9.79	4	2.99	7.53	–69.4586	–23.0848
	Tablet 500 mg	6.79	2	10.40	16.40	53.16642	141.5317
Zolpidem	Tablet 10 mg	8.26	8	5.02	13.00	–39.2252	57.38499
	Tablet 5 mg	5.27	7	3.00	5.65	–43.074	7.210626
Trihexyphenidyl	Tablet 2 mg	1.19	3	0.72	1.10	–39.4958	–7.56303

DPCO: Drug price control order

least costly brand and most costly brand were found for 0.25 mg tablet, that is, –44.1341 and 22.90503, respectively. For diazepam, maximum percent cost variation with least costly brand and most costly brand were found for 2 mg tablet (–65.9864) and 5 mg tablet (43.8848), respectively. For donepezil, both maximum percent cost variation with least costly brand (3.6305) and with most costly brand (8.91719) were found for 10 mg tablet. For escitalopram, maximum percent cost variation with least costly brand was found for 5 mg tablet (–46.7562) and with most costly brand was found for 20 mg tablet (13.4185) respectively. For flunarizine, maximum percent cost variation with least costly brand was found for 5 mg tablet (–48.8889) and with most costly brand was found for 10 mg tablet (18.5745), respectively. For fluoxetine, haloperidol, lithium, lorazepam, phenytoin, and zolpidem, maximum cost variation with least costly brand was found for 10 mg capsule (–48.45), 5 mg tablet (–62.6113), 300 mg tablet (–7.69231), 1 mg tablet (–40.5941), 300 mg extended release capsule (41.01877), and 5 mg tablet (–43.074) [Table 1].

DISCUSSION

In our study, we found wide percent cost variation between DPCO price and branded price (both least and most expensive brand) of commonly used psychiatric medicines. Out of 45 formulations of 18 medicines, for 39 formulations (86.66%), DPCO price is higher than least costly brand available in India. Only for three formulations, DPCO price found lower than most expensive brand available. For one formulation, DPCO price is equal to most expensive brand. Indian government framed DPCO with the objective to improve availability of basic medicines at an affordable price across the country, but in our study, we found that for more than 86% formulations, DPCO price was higher than their respective least costly brand available in Indian market.

There are studies previously done on similar topics. One study done by Shah *et al*. (2019) with the objective to analyze the prices of metformin, losartan, atorvastatin, paracetamol, and aspirin for the doses which are included in the list of DPCO. The branded price of these drugs was compared with prices of DPCO for the same doses of drugs. They found that 11 (44%) out of 25 brands of metformin 500 mg tablet, for losartan 25 mg and 50 mg tablets, 8 (25%) out of 32 and 11 (31.42%) out of 35 were higher, respectively. For atorvastatin 5 mg and 10 mg tablets, 2 (9.52%) out of 21 and 8 (13.55%) out of 59 brands had higher prices. For paracetamol 500 mg tablet, 12 (63.15%) out of 19 brands were priced higher than DPCO list. For aspirin 100 mg tablet and 325 mg tablet, 3 (100%) out of 3 brands and 1 (100%) out of 1 brand had higher prices.[9] Findings of this study suggest that there are many brands which are less costlier than DPCO price. Another study done by Kumar *et al*. (2019) to know the number of antihypertensive drugs brands with price above the recommended DPCO price list 2017. In this study, the data of 30 formulations of 16 antihypertensive drugs were analyzed. They found that out of 1365 formulations, for 831 formulations (60.88%), branded price was less than DPCO price.[1] Above studies suggest that there are many formulations which are less costly as compared to DPCO price. The findings of these studies were in agreement of our study which suggests that not all brands are costlier than DPCO price. There are many brands which are less costly as compared to DPCO price.

Our study has limitation that we have focused only on cost but not on quality. Quality control of medicine is not a regular process in India and data regarding quality of medicine are not freely available in public domain therefore were not able to obtain information about the quality of medicines.

CONCLUSIONS

We found that for more than 86% formulations, DPCO price is higher than least costly brand available in India. The clinicians prescribing these drugs should be aware of these brand formulations to reduce the cost of the drug therapy. Prescribers should prescribe cheaper brands to ensure that patients complete the course of treatment and to reduce patient's out-of-pocket expenditure. Strict drug price regulation needs to be implemented and monitored. The DPCO has not attained its objective completely to bring down prices of medicines. Increased price of essential medicine may lead to failure the goal of universal health coverage. Government authorities need to revise drug pricing policy to bring all brands prices within ceiling price limits.

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