

Cost comparison of commonly used antidepressant drugs with drug price control order in India

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ABSTRACT

Background: Price of a drug is an important factor for compliance to the treatment. So, to overcome the high prices of drugs, National Pharmaceutical Pricing Authority (NPPA) under government of India has issued Drug Price Control Order (DPCO) list containing commonly used drugs. Pharmaceutical companies can be punished if they keep their prices higher than the ceiling price mentioned in the DPCO. To find out the price variations of commonly used antidepressant drugs included in DPCO list of 29th April 2019.

Methods: A list of all oral antidepressant drugs included in DPCO of 29th April 2019 and available in Indian market was procured from medguide India. Analysis of number of total brands following as well as not following DPCO ceiling price was done.

Results: Author found 17 formulations of four antidepressant drugs included in DPCO. Total 556 brands found out of which 84.6% were following the DPCO and 15.4% of brands prices were higher than the ceiling price of DPCO.

Conclusions: Though large number of companies are following the DPCO but still strict regulation is needed to further increase the compliance of guidelines.

Keywords: Antidepressants, Drug price control order, Drug price, National pharmaceutical pricing authority

INTRODUCTION

In the developing country like India, the cost of the various drugs is the very important economic consideration. The pricing of the medicines affects the compliance of the patients to the treatment, as the cost increases compliance of the patient decreases. Cost consideration is especially needed for the drugs given in the diseases which require long term treatment.¹

Major depressive disorder is one such disease that requires long term treatment. The lifetime risk of depression is around fifteen percent. Anti-depressant drugs available in market takes around 3 to 4 weeks to start their action and only one third of the patient got

relief from single drug, so most of the time the combination therapy is needed. If the patient does not response even after 8 weeks of therapy shifting to another medication is needed. So the price consideration of antidepressants drugs is an important issue to maintain compliance of the patients for long term.²

The most commonly prescribed anti-depressants available in market are the tricyclic antidepressants (TCAs), selective serotonin reuptake inhibitors (SSRIs), monoamine oxidase inhibitors (MAOIs), the serotonin-norepinephrine reuptake inhibitors (SNRIs). These drugs are available in various brands and formulation and there is large variation in the prices of these drugs.³

Government of India established an organization called as National Pharmaceutical Pricing Authority (NPPA) to control the prices of drugs in India. It is done under the drug price control order (DPCO) launched in 1995. Its main motive is to keep the prices of the various drugs under check. NPPA also deals with the legal matters related to drug pricing and sponsors various studies related to the cost analysis of drugs. It also seek advice from the central government if needed.⁴ DPCO was started under Section 3 of Essential Commodities Act, 1955 and revised with new changes in 2013. DPCO 2013 list contains schedules formulations of national list of essential medicines (NLEM). This NLEM list decides which drugs are to taken for consideration under DPCO. DPCO-13 was announced by the Ministry of Chemicals and Fertilisers.⁵

The most recent DPCO list was launched on 29 April 2019 under Ministry of Chemicals and Fertilizers and Published in Part II, Section 3, Sub-section (ii) of the Gazette of India, Extraordinary that fixes the ceiling price of the drugs and which was applicable from 1st April 2019.⁶ Ceiling price is the maximum selling price which is set by the government of India and which is applicable throughout the country.⁷ So the aim of this study is to compare the prices of antidepressant drugs as set in the DPCO list with the prices of those drugs as available in market.

METHODS

Study was done in King Georges medical university, Lucknow, India. Study period was of 2 months (July 2019 to August 2019). Authors retrieve the data about the various anti-depressant's drugs in different strengths and brands as available in market from medguideindia.com and compared them to the prices set in the DPCO list 2019. DPCO list of 2019 was downloaded from the NPPA website. The minimum and maximum prices of the drugs available in market were noted after which the number of brands selling with the prices higher than that set by the DPCO list was noted. Then the percentage of drugs not following DPCO was calculated for each drug as follows:

$$= \frac{\text{number of brands not following DPCO}}{\text{total number of brands}} \times 100$$

Inclusion criteria

Only the drugs available in DPCO 19 list were included in the study. All the drugs included are oral preparations.

Exclusion criteria

No FDCs were included in the study.

RESULTS

DPCO 19 list has 4 anti-depressant drugs: amitriptyline, escitalopram, fluoxetine, clomipramine. As per the data authors retrieved for these anti-depressants with similar formulations 556 brands were found. These drugs are available in 17 formulations. Maximum brands were available for escitalopram 40 mg tablet i.e., 89 brands and minimum brands were available for fluoxetine 60 mg tablet i.e., only one brand. Maximum price violation was observed in fluoxetine 40 mg capsule and amitriptyline 25 mg tablet i.e. 37.50% and 33.90 % respectively. The average price violation i.e. the drugs that were not following DPCO order was around 15% and drugs that were following DPCO order were around 85% (Figure 1). All the calculations about the average price violation of various drugs with their formulations are summarized in (Table 1). The maximum price violation was shown by fluoxetine 40 mg capsule i.e. 37.5% and then the amitriptyline 25 mg tablet i.e. 33.9%. Lowest price violation was seen in fluoxetine 60 mg tablet and amitriptyline 10 mg tablet i.e. 0% and 6% respectively. Maximum brands were available for escitalopram 10 mg tablet which showed price violation of 12.36%.

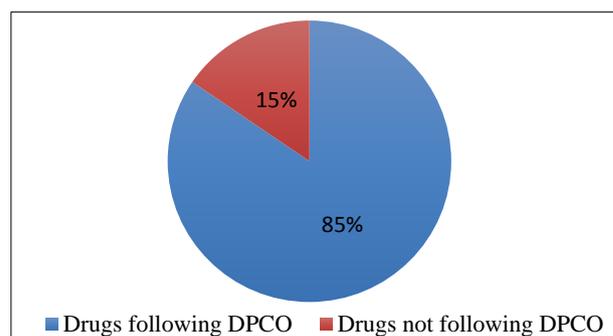


Figure 1: The percentage of all scheduled formulations following and not following DPCO 2019 list.

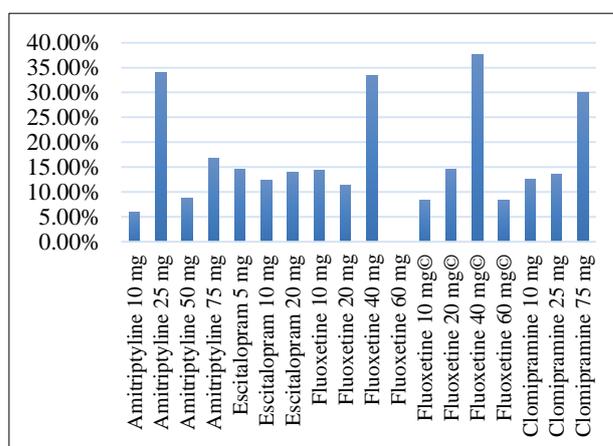


Figure 2: Percentage of drug formulations not following DPCO 2019 list.

Table 1: Price comparison of anti-depressants drugs in the DPCO 2019 list.

Antidepressant drug	Strength	Number of brands	Min. cost (INR)	Max. cost (INR)	DPCO ceiling price (INR)	Number of drugs not following DPCO (INR)	Percentage of drugs not following DPCO (INR)
Amitriptyline	10 mg	50	0.24	11	2.24	3	6.00%
	25 mg	59	0.48	4	2.21	20	33.90%
	50 mg	23	1.7	65	5.68	2	8.70%
	75 mg	30	1.3	6.66	5.49	5	16.67%
Escitalopram	5 mg	48	1.5	14.4	4.47	7	14.58%
	10 mg	89	2.2	24.33	7.93	11	12.36%
	20 mg	57	7.5	13.6	12.52	8	14.04%
Fluoxetine	10 mg	7	1.3	3	2.44	1	14.29%
	20 mg	35	2	7.9	3.88	4	11.43%
	40 mg	3	4	5.4	5.22	1	33.33%
	60 mg	1	6.5		7.24		0.00%
	10 mg©	12	1	3.3	2.91	1	8.33%
	20 mg©	82	0.87	5.28	3.57	12	14.63%
	40 mg©	8	3.6	7.4	5.42	3	37.50%
60 mg©	12	5.5	9.8	9.58	1	8.33%	
Clomipramine	10 mg	8	1.51	2.5	2.46	1	12.50%
	25 mg	22	2.9	5.75	5.43	3	13.64%

Figure 2 shows the percentage of individual drugs not following DPCO 2019 list in the form of the bar chart. The drugs which showed price violation above 30% were clomipramine 75 mg, amitriptyline 25 mg, fluoxetine 40 mg tablet and fluoxetine 40 mg capsule.

DISCUSSION

The DPCO 2019 list was downloaded from NPPA website. Total 4 anti-depressant drugs i.e. amitriptyline, escitalopram, clomipramine and fluoxetine were present in the DPCO list in 17 formulations. Totals 556 brands were found for these 4 drugs among which highest number of brands were available for Escitalopram 10mg i.e. 89 brands. When the prices of the brands of all these 4 drugs were compared with that of DPCO list price highest violation of price was observed in Fluoxetine 40 mg capsule in which 3 among 8 brands i.e. 37% were not following the DPCO list. 33.3% price violation was also observed with fluoxetine 40 mg tablet. Fluoxetine belongs to the SSRI class of antidepressant drugs. SSRIs are the most commonly prescribed antidepressant drugs that acts by inhibiting the serotonin uptake by acting on serotonin reuptake transporter.⁸

Second highest price violation was observed with amitriptyline 25 mg tablet that is around 33.9%. It was synthesized by 59 brands among which 20 brands were not following DPCO order. Amitriptyline belongs to the class of tricyclic anti-depressant and fluoxetine to the class of selective serotonin reuptake inhibitor. Amitriptyline was previously considered as one of the best TCA for the treatment of depression. Due to the

development of serious side effects its use became less popular these days and is now replaced by SSRIs.⁹

The study has been done previously to assess the cost variation among different anti-depressants drugs present in market and found that highest percentage cost variation was present in amitriptyline 50 mg and amitriptyline 75 mg. The other drugs in which they observed high cost variations were bupropion and dosulepin but these drugs are still not included in the DPCO list.²

DPCO list was launched by NPPA in authorization by government of India in order to regulate the prices of essential medicines in the country and to provide medicines to citizen of country at affordable prices. Major depressive disorder is one of the most common neuropsychiatric disorder and is one of the major causes of disability with the prevalence of around 17%. Still there are only 4 anti-depressant drugs which are included in the DPCO list and no atypical anti-depressants with fewer side effects like bupropion, mirtazapine are included.⁹ A study was conducted to look for the prescription pattern of drugs in eastern India and they found that Sertraline was the most commonly prescribed Anti-depressant drug.¹⁰ Another study conducted to look for the prescription pattern of anti-depressants in northern India and they found that Duloxetine was the most commonly prescribed anti-depressant drug which is also not included in the DPCO list.¹¹

Despite of all efforts of Government of India the overall price violation as per this study is 15%. After the government order in 2013 NPPA is authorized to include even non NLEM medicine in the DPCO list. The

pharmaceutical companies which do not follow the DPCO price list are liable to deposit the overcharged price to the government or the imprisonment from 7 months to 3 years. Still the pharmaceutical companies are manufacturing drugs with higher price because of the increasing need. If the government puts pressure on these pharmaceutical companies strictly and stop them it could also affect the health care need of the society as the less number of drugs will be available.¹²

CONCLUSION

Present study demonstrated that, large number of companies are following the DPCO but still some pharmaceutical companies violating guideline in term of cost. As it was found in the study maximum brand available in market are of amitriptyline and fluoxetine, the brands of these two drugs showing maximum price violation as compared to DPCO guidelines. It may affect the compliance, so still strict regulation is needed to follow the guidelines.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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