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Original Research Article

Evaluation of brand, ceiling and generic price differences in anti-epileptic drugs marketed in India: a novel cost variation analysis

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ABSTRACT

Background: Epilepsy affects 6–10 million people in India, where over 60% of healthcare spending is out-of-pocket. Wide price differences in branded antiepileptic drugs (AEDs) can hinder adherence and increase financial burden. While DPCO sets ceiling prices and Jan Aushadhi offers low-cost generics, no Indian study has compared AED prices across both schemes. To assess price variation among 17 commonly used AEDs and compare brand prices with DPCO ceilings and Jan Aushadhi rates.

Methods: A cross-sectional cost analysis was conducted using MRPs from the Current Index of Medical Specialties, NPPA database and Jan Aushadhi Scheme database. Price variation and ratios were calculated. Median brand prices were benchmarked against DPCO and JAS prices to evaluate cost gaps.

Results: Pregabalin 75 mg capsules showed the highest inter-brand cost variation (564.7%), followed by pregabalin 150 mg tablets (487.9%) and levetiracetam 750 mg tablets (370.4%). Phenytoin 300 mg ER tablets were priced 39.63% above the DPCO ceiling and sodium valproate 200 mg tablets exceeded it by 36.7%. Branded AEDs were 0.7 to 8 times costlier than Jan Aushadhi generics; pregabalin 75 mg capsules were 667.73% more expensive.

Conclusions: This first dual-layered analysis of AED pricing in India shows wide price variation and poor compliance with controls. Expanding DPCO coverage, promoting generics and educating prescribers on drug costs can improve affordability and adherence.

Keywords: Anti-epileptic drugs, Cost variation, Current index of medical specialties, Drugs prices control order, Jan aushadhi scheme, Pharmacoeconomics

INTRODUCTION

Epilepsy is a chronic neurological disorder characterized by recurrent, unprovoked seizures.¹ It is one of the most common serious brain conditions, affecting about 50 million people worldwide, roughly 80% of whom reside in low- and middle-income countries.² In India, community surveys estimate epilepsy prevalence at 5–10 per 1000 population ($\approx 1\%$), corresponding to on the order of 6–10 million people, about one-fifth of the global epilepsy burden.^{1,3} Effective antiepileptic drug (AED) therapy can render $\sim 70\%$ of patients seizure-free, but long delays in diagnosis, stigma and resource gaps mean many patients in India remain untreated or undertreated.^{1,2} Because

epilepsy often begins early in life and requires prolonged (often lifelong) medication, its social and economic burdens are substantial.^{3,4} Indian neurologists note that epilepsy is a leading cause of disability and imposes a “substantial social and economic burden” in the country.¹ A multicentric Indian study found the mean annual cost per epilepsy patient was $\sim ₹13,755$ (US \$344) and the national epilepsy treatment cost about ₹68.75 billion ($\approx$ \$1.7 billion, $\sim 0.5\%$ of GDP).³ These costs hit hard in India, where health care financing is predominantly out-of-pocket: roughly 60–62% of all health expenditures are paid directly by households.^{5,6} In this context of limited insurance coverage, physician awareness of drug prices and use of cost-effective alternatives is critical to avoid

impoverishing patients.⁵ 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.⁷ The National Pharmaceutical Pricing Authority (NPPA) was established on August 29, 1997, to regulate the prices of pharmaceutical drugs in India. The implementation of the National Pharmaceutical Pricing Policy, 2012 and the Drugs Prices Control Order (DPCO), 2013 was brought about by NPPA.⁸ "Ceiling price" means a price fixed by the government in accordance with the provisions of the DPCO.

To increase the availability of generic medicines to the population, the Government of India launched the Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) also known as the Jan Aushadhi Scheme (JAS), led by the Bureau of Pharma PSUs of India (BPPI) under Department of Pharmaceuticals in the year 2008.⁹ Generic drug stores were opened across the nation to provide affordable medicines to the masses. However, Majority of the stores are non-functional due to various issues such as lack of support from the government, flawed supply chain and its poor management, non-prescription of generic medicines, poor perspectives and lack of awareness.⁸ Despite price controls made by government on some essential medicines, the majority of marketed drugs are still outside price regulation.^{4,10} Consequently, different brands of the same AED can have dramatically diverse prices. Empirical analyses confirm this disparity: one recent survey of Indian market prices found cost variations exceeding 300% for diazepam 5 mg tablets and ~173% for carbamazepine syrup among brands.¹⁰ Such price fluctuations can impact treatment outcomes and adherence: expensive medications and repeated changes to high-priced brands have been associated with patient nonadherence, threatening breakthrough seizures and suboptimal control.^{4,10}

In developing nations, pharmacoeconomics is crucial to medical practice. The cost of the medications has a significant impact on the patient's adherence to their treatment. In India, most drugs are available in branded forms and furthermore clinicians largely prescribe them in brand names.¹¹ 'Cost analysis' is a type of partial pharmacoeconomic evaluation that compares the costs of two or more alternatives without considering the outcomes.¹² In the context of pharmaceuticals, this analysis involves comparing the costs of different brands of the same drug, which are expected to provide the same therapeutic outcome. By analyzing the costs of these alternatives, researchers can identify the phenomenon of "inter-brand price variation," which can place a significant financial burden on patients and raise moral and ethical concerns.⁷ While some previous studies have shown that there is indeed a wide variation in brand prices in the Indian market, the data is still limited and these studies have focused on drugs in a single therapeutic area. Assessing the brand price variation across multiple therapeutic areas would provide a more comprehensive

understanding of the actual state of price variations and the impact of current drug pricing policies.^{7,12}

To our knowledge, this is the first study in India that has systematically compared anti-epileptic drug prices not only across brands but also in relation to both DPCO ceiling prices and Jan Aushadhi generic prices. While previous studies have focused on inter-brand cost variation alone, this dual-layered comparison provides a more comprehensive picture of price disparities and real-world affordability. The aim of this study was to compare the prices of commonly prescribed anti-epileptic drugs (AEDs) from various brands that are available in the Indian pharmaceutical market with the ceiling prices set by the Drugs Prices Control Order (DPCO) and the generic prices under the Jan Aushadhi Scheme (JAS). These findings will highlight potential cost savings and inform cost-conscious prescribing in India, where most patients pay entirely out-of-pocket and drug cost can be a barrier to sustained epilepsy care.

METHODS

Study design

This was a cross-sectional observational study conducted to evaluate the cost variation of anti-epileptic drugs (AEDs) available in the Indian pharmaceutical market.

Selection of drugs

A total of 17 commonly prescribed anti-epileptic drugs were selected based on their frequency of use in clinical practice. Both first-line and second-line AEDs were included, in various dosage forms and strengths (e.g., tablets, syrups).

Data source

The Maximum Retail Prices (MRPs) of different branded formulations of the selected anti-epileptic drugs were collected from the following sources:

Current index of medical specialties

National pharmaceutical pricing authority (NPPA) database for price control references.¹³ Generic prices as per Jan aushadhi scheme¹⁴

Inclusion criteria

Anti-epileptic drugs available in oral, topical or injectable dosage forms (e.g., tablets, capsules, injections etc.)

Exclusion criteria

Drugs with only one brand and one price. Fixed-dose combinations. Drugs not available in standard strengths or formulations.

Data collection and analysis

For each drug (specific strength and formulation), the following data points were collected. Name of the anti-epileptic drug. Strength and dosage form. Number of brands available. Minimum and maximum prices per tablet. The median cost of the drugs per tablet/ml. The average cost of the drugs per tablet/ml. The percentage cost variation was calculated using the formula.

$$\text{Cost Variation (\%)} = \frac{(\text{Maximum Price} - \text{Minimum Price})}{\text{Minimum Price}} \times 100$$

Additionally, the cost ratio was calculated as.

$$\text{Cost Ratio} = \frac{\text{Maximum Price}}{\text{Minimum Price}}$$

Statistical analysis was done using Microsoft Excel 2021 to determine the extent of price variation for each drug. Drugs with a cost variation >100% were considered to have significant price disparities.

RESULTS

A total of 17 commonly prescribed anti-epileptic drugs (AEDs) across various strengths and formulations were analyzed for cost variation. The analysis revealed substantial disparities in prices among different brands of the same drug. Price differences were found not only in tablets but also in syrups, injections and extended-release formulations. This variation underscores a critical concern for clinicians and patients alike, particularly in India, where the burden of out-of-pocket healthcare expenses is high and medication adherence is often compromised due to cost.

Table 1 presents a detailed cost variation analysis, showing a wide range of price discrepancies across different brands of the same AED. The highest cost variation was seen in Pregabalin 75 mg capsules, with a staggering 564.74% variation, followed by Pregabalin 150 mg tablets (487.91%) and Levetiracetam 750 mg tablets (370.44%). Among the older AEDs, Phenobarbitone 60 mg tablets showed a variation of 175%, while Clobazam 5 mg tablets showed a 250.37% price difference.

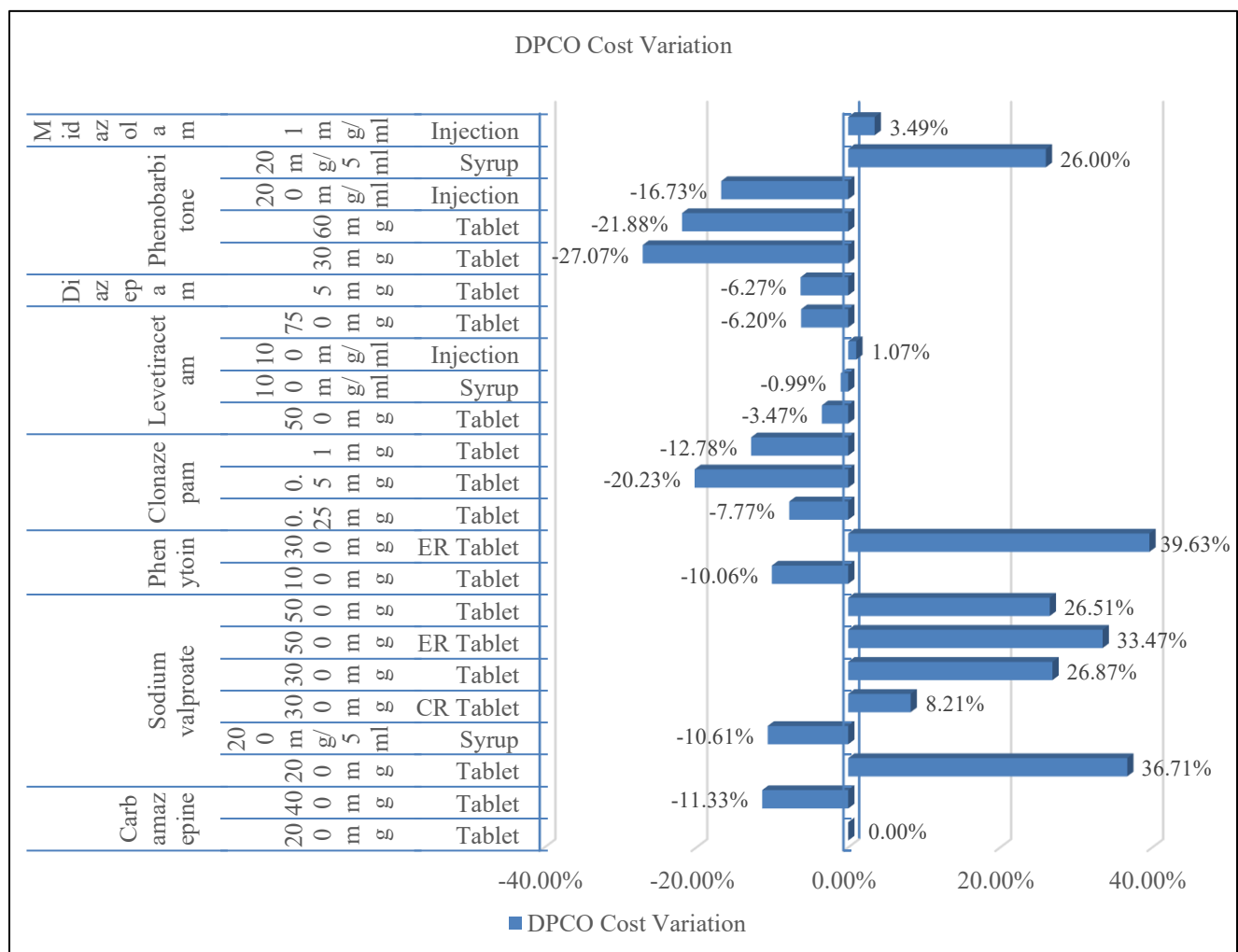


Figure 1: Cost variation between median brand price and DPCO ceiling price.

Table 2 shows the mean, median and standard deviation for each strength of the included drugs. The highest Mean price was observed for Levetiracetam 1000 mg ER tablet with 37.20 $\pm$ 3.11 and a median price of ₹37.20 followed Pregabalin 150mg Tablet with 32.86 $\pm$ 33.0 while median being ₹17.57 followed by Levetiracetam 750 mg tablets had a mean price of ₹26.25 and a standard deviation of ₹21.46, demonstrating the presence of extreme outliers in brand pricing.

Figure 1 compares the median brand prices with the DPCO 2013 ceiling prices. Several drugs were found to be priced above the DPCO ceiling with the highest being Phenytoin 300 mg ER tablet about 39.63% higher than the regulated ceiling price followed by Sodium Valproate 200 mg

tablets, where the median brand price was higher by 36.71%, Sodium Valproate 500 mg ER tablet by 33.47%. Phenobarbitone 30 mg was 27.07% below the ceiling price followed by Phenobarbitone 60 mg by 21.88%.

The analysis of table 3 reveals significant cost differences between median brand price and generic price available under the Jan Aushadhi Scheme (JAS). Several drugs had over 300% higher prices for branded formulations compared to their generic counterparts. In our study, Pregabalin 75 mg capsules were 667.73% more expensive than the JAS price followed by Clonazepam 0.5 mg tablets (409.09%). Diazepam 10 mg tablet was the only drug with median brand price being 28% lower than the generic price.

Table 1: Cost variation analysis of AED's.

Drug name	DDD	Dosage form	Avg price per tablet	Number of brands	Price ratio	Cost variation
Carbamazepine	200 mg	Tablet	1.29	6	1.68	67.85%
	300 mg	Tablet	1.91	2	2.20	119.90%
	400 mg	Tablet	2.62	4	1.38	38.30%
Sodium valproate	1000 mg	Tablet	9.04	4	2.12	112.02%
	200 mg	CR Tablet	3.47	2	1.09	9.42%
	200 mg	EC Tablet	2.51	3	1.53	53.05%
	200 mg	Tablet	2.16	4	2.46	145.71%
	200 mg/5 ml	Syrup	0.65	3	1.16	15.84%
	250 mg	ER Tablet	11.86	5	3.12	212.21%
	250 mg	Tablet	13.18	7	2.54	153.88%
	300 mg	CR Tablet	7.06	2	1.10	10.43%
	300 mg	Tablet	5.68	3	1.27	26.81%
	500 mg	CR Tablet	10.94	2	1.46	45.89%
	500 mg	EC Tablet	7.59	2	1.13	13.35%
	500 mg	ER Tablet	21.61	5	3.13	213.16%
	500 mg	Tablet	20.65	12	2.75	175.39%
	750 mg	Tablet	12.90	3	1.36	35.66%
Phenytoin	100 mg	Tablet	1.70	4	1.13	13.33%
	300 mg	ER Tablet	7.36	2	1.21	20.54%
Pregabalin	150 mg	Capsule	82.31	4	5.88	487.91%
	75 mg	Capsule	63.15	4	6.65	564.74%
Clonazepam	75 mg	ER Tablet	10.40	2	1.62	62.45%
	0.25 mg	Tablet	1.91	12	2.03	102.55%
	0.5 mg	Tablet	3.16	17	2.03	102.63%
	1 mg	Tablet	4.20	10	1.48	47.69%
Lamotrigine	2 mg	Tablet	5.40	10	2.10	110.04%
	100 mg	DS Tablet	28.42	2	1.35	35.23%
	100 mg	Tablet	18.39	4	1.68	68.10%
	25 mg	Tablet	4.00	3	1.41	41.38%
Gabapentin	50 mg	Tablet	10.99	4	1.46	46.49%
	100 mg	Tablet	5.80	6	1.50	50.00%
	300 mg	Capsule	14.88	3	1.25	24.52%
	300 mg	Tablet	11.00	6	1.38	38.18%
Levetiracetam	500 mg	FC Tablet	12.40	4	1.86	86.25%
	500 mg	Tablet	12.96	8	1.12	11.86%
	1000 mg	ER Tablet	35.00	2	1.13	12.57%
	1000 mg	Tablet	24.00	4	1.16	16.46%
	100 mg/ml	Syrup	4.00	3	1.16	16.00%
	100 mg/ml	Injection	24.34	2	1.06	5.86%
	250 mg	Tablet	6.41	7	1.05	4.69%
	250 mg	FC Tablet	6.50	2	1.62	61.54%
	500 mg/5 ml	Syrup	3.90	2	1.02	2.31%

Continued.

Drug name	DDD	Dosage form	Avg price per tablet	Number of brands	Price ratio	Cost variation
Topiramate	750 mg	FC-Tablet	18.47	4	1.07	6.69%
	750 mg	Tablet	20.28	7	4.70	370.44%
	100 mg	Tablet	10.79	4	1.46	46.47%
	25 mg	Tablet	4.70	4	1.96	95.82%
	50 mg	Tablet	8.40	4	1.82	81.80%
Clobazam	5 mg	Tablet	0.00	8	3.50	250.37%
	10 mg	Tablet	0.00	9	2.61	160.54%
	20 mg	Tablet	0.00	2	1.68	68.33%
Lacosamide	100 mg	Tablet	13.50	3	1.23	22.73%
	50 mg	Tablet	8.70	2	1.45	45.00%
Lorazepam	1 mg	Tablet	2.67	12	1.68	68.24%
	2 mg	Tablet	2.94	12	2.77	176.86%
	2 mg/ml	Injection	8.53	3	1.22	22.32%
Oxcarbazepine	450 mg	Tablet	14.30	5	2.24	123.81%
	600 mg	FC tablet	16.80	2	1.44	44.32%
	600 mg	Tablet	11.50	4	1.89	88.70%
	150 mg	Tablet	5.40	5	1.50	50.45%
	150 mg	FC tablet	6.25	2	1.01	0.64%
	150 mg	ER Tablet	7.40	2	1.20	20.13%
	300 mg	Tablet	7.80	6	1.47	47.38%
	300 mg	FC tablet	9.90	2	1.24	24.34%
Diazepam	300 mg	ER-Tablet	13.80	2	1.03	2.77%
	5 mg	Tablet	1.56	3	1.43	43.33%
	10 mg	Tablet	1.23	2	1.34	34.15%
Phenobarbitone	30 mg	Tablet	0.63	7	2.28	127.50%
	60 mg	Tablet	1.01	7	2.75	175.00%
	200 mg/ml	Injection	18.76	4	1.94	94.30%
	20 mg/5 ml	Syrup	0.49	1	1.56	56.12%
Zonisamide	25 mg	Capsule	5.10	3	1.92	91.51%
	100 mg	Capsule	9.27	4	2.23	123.35%
	50 mg	Capsule	5.70	3	1.89	89.47%
Midazolam	1 mg/ml	Injection	6.24	1	1.00	0.03%

*DDD-Defined Daily Dose, ER Tablet: Extended-Release Tablet, CR Tablet: Controlled Release Tablet, EC Tablet: Enteric Coated Tablet, FC Tablet: Film Coated Tablet, DS Tablet: Dispersible Tablet.

Table 2: Mean, median and standard deviation (SD) of AED's.

Drug name	DDD	Dosage form	Max. price	Min. price	Mean Price	Median price	SD
Carbamazepine	200 mg	Tablet	2.17	1.29	1.64	1.60	0.29
	300 mg	Tablet	4.20	1.91	3.05	3.05	1.61
	400 mg	Tablet	3.62	2.62	3.16	3.20	0.41
Sodium valproate	1000 mg	Tablet	19.16	9.04	14.47	14.85	4.18
	200 mg	CR Tablet	3.80	3.47	3.64	3.64	0.23
	200 mg	EC Tablet	3.84	2.51	3.30	3.42	0.56
	200 mg	Tablet	5.30	2.16	4.36	4.99	1.47
	200 mg/5 ml	Syrup	0.65	0.56	0.60	0.59	0.04
	250 mg	ER Tablet	11.86	3.80	7.56	7.20	2.88
	250 mg	Tablet	13.10	5.16	7.27	6.68	2.52
	300 mg	CR Tablet	7.06	6.40	6.72	6.72	0.47
	300 mg	Tablet	7.20	5.68	6.21	5.76	0.85
	500 mg	CR Tablet	10.94	7.50	9.22	9.22	2.43
	500 mg	EC Tablet	8.60	7.59	7.97	7.74	0.54
	500 mg	ER Tablet	21.61	6.90	13.23	12.60	5.32
	500 mg	Tablet	20.65	7.50	12.12	10.45	4.26
	750 mg	Tablet	17.50	12.90	14.46	13.00	2.62
Phenytoin	100 mg	Tablet	1.70	1.50	1.60	1.61	0.10
	300 mg	ER Tablet	7.36	6.10	6.73	6.73	0.88
Pregabalin	150 mg	Capsule	82.31	14.00	32.86	17.57	33.00
	75 mg	Capsule	63.15	9.50	21.80	16.89	18.62

Continued.

Drug name	DDD	Dosage form	Max. price	Min. price	Mean Price	Median price	SD
Clonazepam	75 mg	ER Tablet	16.90	10.40	13.65	13.65	4.59
	0.25 mg	Tablet	2.70	1.33	1.94	1.90	0.42
	0.5 mg	Tablet	3.85	1.90	2.81	2.80	0.64
	1 mg	Tablet	4.73	3.20	4.32	4.23	0.76
	2 mg	Tablet	10.80	5.14	7.03	7.00	1.82
Lamotrigine	100 mg	DS Tablet	28.42	21.01	24.71	24.71	5.23
	100 mg	Tablet	21.01	12.50	18.22	19.69	4.01
	25 mg	Tablet	5.66	4.00	5.05	5.50	0.91
	50 mg	Tablet	10.99	7.50	10.42	10.60	2.27
Gabapentin	100 mg	Tablet	7.50	5.00	5.99	5.75	0.92
	300 mg	Capsule	14.88	11.95	13.27	13.00	1.48
	300 mg	Tablet	15.20	11.00	13.63	14.00	1.46
Levetiracetam	500 mg	FC Tablet	21.42	11.50	16.06	15.65	4.85
	500 mg	Tablet	13.20	11.80	12.57	12.67	0.51
	1000 mg	ER Tablet	39.40	35.00	37.20	37.20	3.11
	1000 mg	Tablet	27.95	24.00	25.36	24.75	1.77
	100 mg/ml	Syrup	4.41	3.80	4.06	4.00	0.30
	100 mg/ml	Injection	24.34	22.99	23.67	23.67	0.95
	250 mg	Tablet	6.70	6.40	6.27	6.40	0.40
	250 mg	FC Tablet	10.50	6.50	8.50	8.50	2.82
	500 mg/5 ml	Syrup	3.99	3.90	3.94	3.94	0.06
	750 mg	FC Tablet	19.50	18.28	18.89	18.91	0.61
	750 mg	Tablet	74.80	15.90	26.25	18.46	21.46
Topiramate	100 mg	Tablet	15.80	10.79	14.58	14.77	3.07
	25 mg	Tablet	7.50	3.83	5.43	5.20	1.57
	50 mg	Tablet	14.90	8.20	10.37	9.20	3.12
Clobazam	5 mg	Tablet	11.83	3.38	5.70	5.22	2.79
	10 mg	Tablet	14.85	5.70	9.13	8.98	2.94
	20 mg	Tablet	37.87	22.50	30.19	30.19	10.87
Lacosamide	100 mg	Tablet	13.50	11.00	12.00	11.50	1.32
	50 mg	Tablet	8.70	6.00	7.35	7.35	1.90
Lorazepam	1 mg	Tablet	2.67	1.59	1.91	1.80	0.48
	2 mg	Tablet	4.20	1.52	2.57	2.55	0.62
	2 mg/ml	Injection	10.00	8.18	8.90	8.50	0.96
Oxcarbazepine	450 mg	Tablet	18.80	8.40	14.10	14.30	4.27
	600 mg	FC tablet	24.25	16.80	20.52	20.52	5.26
	600 mg	Tablet	21.70	11.50	16.22	15.84	4.27
	150 mg	Tablet	7.25	4.82	6.01	6.10	0.94
	150 mg	FC tablet	6.29	6.25	6.27	6.27	0.02
	150 mg	ER Tablet	7.40	6.16	6.78	6.78	0.87
	300 mg	Tablet	11.30	7.67	9.26	8.90	1.55
	300 mg	FC tablet	12.31	9.90	11.11	11.11	1.70
Diazepam	300 mg	ER Tablet	13.80	13.43	13.61	13.61	0.26
	5 mg	Tablet	1.75	1.22	1.51	1.56	0.26
	10 mg	Tablet	1.65	1.23	1.44	1.44	0.29
Phenobarbitone	30 mg	Tablet	1.37	0.60	0.98	0.97	0.30
	60 mg	Tablet	2.20	0.80	1.49	1.50	0.51
	200 mg/ml	Injection	24.87	12.80	18.36	18.76	5.06
	20 mg/5 ml	Syrup	0.77	0.49	0.63	0.63	0.19
Zonisamide	25 mg	Capsule	5.10	2.66	4.15	4.70	1.30
	100 mg	Capsule	20.70	9.27	14.66	14.34	6.08
	50 mg	Capsule	10.80	5.70	8.60	9.30	2.62
Midazolam	1 mg/ml	Injection	6.24	6.24	6.23	6.23	0.00

*ER Tablet: Extended-Release Tablet, CR Tablet: Controlled Release Tablet, EC Tablet: Enteric Coated Tablet, FC Tablet: Film Coated Tablet, DS Tablet: Dispersible Tablet.

Table 3: Cost variation between median brand price and Jan Aushadhi Scheme (JAS) generic price.

Drug name	DDD	Dosage form	Median price	JAS Generic Price	JAS price variation
Sodium valproate	200 mg	EC Tablet	3.42	1.7	101.18%
	200 mg/5 ml	Syrup	0.59	0.275	114.55%
Phenytoin	100 mg	Tablet	1.61	0.55	192.73%
Pregabalin	75 mg	Capsule	16.89	2.2	667.73%
Clonazepam	0.5 mg	Tablet	2.80	0.55	409.09%
	1 mg	Tablet	4.23	0.88	380.68%
Lamotrigine	100 mg	Tablet	19.69	4.4	347.50%
	25 mg	Tablet	5.50	1.5	266.67%
	50 mg	Tablet	10.60	2	430.00%
Gabapentin	100 mg	Tablet	5.75	1.54	273.38%
	300 mg	Capsule	13.00	2.75	372.73%
Levetiracetam	500 mg	Tablet	12.67	6.82	85.70%
	1000 mg	ER Tablet	37.20	12.5	197.60%
	1000 mg	Tablet	24.75	12	106.25%
	100 mg/ml	Syrup	4.00	0.85	370.59%
	250 mg	Tablet	6.40	3	113.33%
	750 mg	Tablet	18.46	9	105.11%
Topiramate	100 mg	Tablet	14.77	3	392.17%
	50 mg	Tablet	9.20	2	360.00%
Clobazam	5 mg	Tablet	5.22	1.5	248.00%
	10 mg	Tablet	8.98	3.2	180.63%
Lacosamide	100 mg	Tablet	11.50	5.6	105.36%
Lorazepam	1 mg	Tablet	1.80	1.1	63.64%
	2 mg	Tablet	2.55	1.2	112.50%
Oxcarbazepine	150 mg	Tablet	6.10	3.85	58.39%
	300 mg	Tablet	8.90	4	122.45%
Diazepam	5 mg	Tablet	1.56	0.6	159.33%
	10 mg	Tablet	1.44	2	-28.00%
Phenobarbitone	30 mg	Tablet	0.97	0.8	21.25%
	60 mg	Tablet	1.50	0.93	61.29%
	200 mg/ml	Injection	18.76	0	NA
	20 mg/5ml	Syrup	0.63	0	NA
	100 mg	Capsule	14.34	11	30.36%
	50 mg	Capsule	9.30	5.86	58.70%

*ER Tablet: Extended-Release Tablet, EC Tablet: Enteric Coated Tablet.

DISCUSSION

This study highlights marked cost disparities among brands of anti-epileptic drugs (AEDs) in India and reveals inconsistent adherence to price regulations and underutilization of low-cost generics. Despite regulatory ceilings under the drugs price control order (DPCO), many formulations exceeded these limits and branded options remained substantially more expensive than generics available through the Jan Aushadhi Scheme (JAS). These findings underscore the need for stronger policy enforcement, increased generic prescribing and enhanced physician and patient awareness to reduce the economic burden of epilepsy care.

Our analysis found extreme variability in brand pricing: Pregabalin 75 mg capsules showed up to a 564.74% cost variation and Pregabalin 150 mg tablets by 487.91%, Levetiracetam 750 mg tablets varied by 370.44% which was found in accordance with the study done by Agrawal et al.¹⁵ Similarly, Allisabanavar et al, reported Lorazepam

2 mg tablets up to 213.63% which was analogous to our study (176.86%).¹⁶ A long established study also documented Carbamazepine conventional 200mg tablets varied by 101.6% which was similar to our study of about 67.85%.¹⁷ Wagle et al, also reported Levetiracetam 250 mg tablets cost spreads exceeding 1000%, while our study observed considerable lower observations of about 4.69%.¹⁷ Such wide inter brand differences can directly impact adherence, as high out of pocket costs are a known barrier to continuous therapy in epilepsy.¹⁸

Although the revised DPCO 2013 aims to cap prices of essential drugs, our data show many AEDs priced above these ceilings. In our study findings, the highest premium was observed for phenytoin 300 mg ER tablet whose median price exceeded the DPCO ceiling by 39.63% followed by sodium valproate 200 mg tablets by 36.7%, by sodium valproate 500 mg tablets by 33.47%. These exceedances largely stem from DPCO's limited coverage of specific formulations, lagging price revisions, weak enforcement and unregulated distributor–retailer markups

that allow final MRPs to exceed ceiling limits. A review of NPPA data indicates that over 80% of marketed medicines remain outside mandatory price control.¹⁹ Moreover, extended release and non-oral formulations are often excluded, allowing manufacturers to circumvent ceilings. These gaps in regulation suggest an urgent need to expand the list of scheduled formulations and strengthen enforcement mechanisms.

Comparison with Jan Aushadhi Scheme (JAS) prices revealed that branded AED's cost up to 0.7–8 times more than their generic equivalents. Pregabalin 75 mg capsules were priced at 667.73% premium compared to JAS prices, while clonazepam 0.5 mg tablets were priced at 409.09% premium. These premiums were similar to the brand prices but slightly lower, in the study conducted by Arya et al, the premiums were 347.59% and 263.63% respectively.¹⁸ Significant cost savings have been observed in India when substituting branded antiepileptic drugs (AEDs) with generic alternatives. For instance, a study conducted in Pune assessed 150 pediatric epilepsy patients treated with low-cost branded generics like oxcarbazepine and sodium valproate. The study found that 96.66% of patients were seizure-free at six months, with minimal and tolerable adverse effects, indicating that cost-effective treatment did not compromise efficacy.²⁰ Yet, low awareness of JAS outlets and concerns about generic quality limit uptake, emphasizing the need for educational campaigns and supply chain improvements.

Physicians in India predominantly prescribe by brand name, influenced by marketing and limited training in pharmacoeconomics.¹⁹ Integrating drug price information into electronic prescribing platforms and medical curricula can foster cost conscious decisions. Studies in tertiary care settings demonstrate that real time price alerts at prescription significantly shift choices toward lower cost generics, reducing patient expenditure by nearly 30%.²¹

Our study has several notable strengths. First, it provides a comprehensive, multi layered cost analysis of 17 commonly prescribed AEDs across a wide range of strengths and formulations, capturing tablets, syrups and injectable forms. Second, to our knowledge, this is the first Indian study to benchmark brand to brand price variation not only against each other but also against DPCO ceiling prices and Jan Aushadhi generic prices, offering a uniquely policy relevant perspective on affordability. Third, by including both mean/median price metrics and cost-ratio calculations, we deliver robust, easily interpretable measures of variation that can directly inform prescriber choices and formulary decisions.

However, several limitations should be acknowledged. Our analysis relies solely on publicly available list prices (MRPs), which may not reflect discounts, rebates or regional procurement rates thus actual patient or hospital expenditures could differ. The cross sectional design captures prices at a single time point and cannot account for temporal fluctuations or future DPCO revisions. We did

not assess clinical outcomes or adherence data, so the direct impact of price variation on patient behavior remains speculative. Finally, exclusion of fixed dose combinations and drugs with only one brand may limit the generalizability of our findings to all AEDs used in practice.

To bridge affordability gaps, policymakers should revise the DPCO to include all formulations and strengths of essential AEDs, enhance monitoring and penalties for noncompliance and expand the JAS network in underserved areas. Future research should assess the impact of pricing disparities on seizure outcomes, adherence rates and catastrophic health spending in diverse Indian populations.

CONCLUSION

In conclusion, our study highlights pronounced price disparities among multiple brands of anti-epileptic drugs in India, with variations reaching several hundred percent even for long established therapies. By uniquely comparing market prices not only against one another but also against government mandated DPCO ceilings and Jan Aushadhi generic rates, we uncovered that many branded formulations exceed regulated ceilings and cost upto eight times more than public sector generics. These findings underscore the urgent need to tighten enforcement of existing price controls, to expand the range of AEDs covered under DPCO and to strengthen the Jan Aushadhi network to ensure broader availability of affordable generics. Encouraging prescribers to consider price information at the point of care and integrating cost transparency into clinical decision support tools could foster more economical prescribing. Ultimately, such multifaceted policy and practice interventions have the potential to enhance treatment adherence, reduce out of pocket spending and improve long term seizure control for patients with epilepsy across India.

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