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**Review Article**

# A cost variation analysis of chronic obstructive pulmonary disorder medications in the Indian market concerning Jan Aushadhi medications and their branded counterparts

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## ABSTRACT

Medications and pharmaceutical expenses constitute a significant portion of out-of-pocket health expenditures for households in India, posing a substantial financial burden. The objective of this study was to assess the cost differences among drugs utilized in the treatment of chronic obstructive pulmonary disorder (COPD), specifically comparing those available at Jan Aushadhi pharmacies with various branded drug formulations. In the study, we calculated the cost differences (in Indian Rupees), cost ratios, and cost variations by contrasting the cost of generic Jan Aushadhi medications with the most expensive and least expensive branded medications in the same category. Our study revealed that the price of branded drugs prescribed for obstructive pulmonary conditions was higher than that of generic drugs purchased from Jan Aushadhi pharmacies except in the case of doxophylline 400 mg tablet. The highest cost difference was observed in the combination drug of formoterol 6 mcg + fluticasone propionate 250 mcg inhaler (740 and 290). Cost variance and cost ratio were highest in salbutamol 4 mg tablets (2386%) and (24.86) respectively. Findings indicate that across all classes of drugs investigated, the costs associated with generic drugs in Jan Aushadhi centers were markedly lower than those associated with branded drugs. Medications offered by Jan Aushadhi pharmacies are more cost-effective than their branded equivalents, rendering COPD treatment more accessible and affordable for individuals with limited financial means.

**Keywords:** Jan Aushadhi, COPD, Generic medications, Cost analysis, Out of pocket expenditure, Cost minimization

## INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a complex illness state marked by persistent airflow obstruction that is typically progressive. Smoking and exposure to noxious particles or gases are linked to the development of COPD. The typical signs of COPD include dyspnea, weakness, chronic cough, and sputum production.[1] Although smoking has been identified as the primary factor contributing to the increased frequency of COPD worldwide, a combination of genetic and environmental risk factors also plays a role.

COPD is one of the main causes of chronic morbidity and mortality as well as a leading global public health issue. Given that COPD is currently the fourth most common cause of death worldwide, future increases in both its prevalence and mortality are likely.[2] According to the World Health Organization (WHO) Global Burden of Disease Study 2016, there were 251 million COPD patients worldwide, and low- and middle-income countries accounted for more than 90% of COPD-related fatalities.[3] Most clinical trials and COPD prevalence surveys conducted across the globe included patients who currently smoke or had a history of smoking. Consequently, other risk factors related to lifestyle and environment were ignored. Recent data indicates in low- and middle-income

countries (LMICs), the prevalence of non-smoking-related COPD is larger than previously thought, and it accounts for one-third to one-fourth of all cases of COPD.[4] In a study conducted on 1200 slum residents in Pune, Maharashtra, it was observed that 69% of COPD sufferers were found to have never smoked.[5] In addition to smoking, other factors that significantly contribute to the onset and course of COPD in LMICs include exposure to bacteria and viruses, different types of dust, chemicals, vapors, fumes in the workplace, and other pollutants. It has been found that exposure to household pollution (biomass fuel and kerosene lamps) is another important factor in developing nations that results in COPD.[6] The low socioeconomic level makes things worse in LMICs since it can exacerbate lung disorders caused by things like poor nutrition, low birth weight, indoor and outdoor pollution exposure, and inadequate access to healthcare.

There has been a noticeable rise in the prevalence of respiratory illnesses in India, the most populous country worldwide. India contributes to over 20% of COPD cases globally and has an 8.7% mortality rate, according to the Global Burden of Diseases, Injuries, and Risk Factors Study (GBD) of 2016.[3] In 2016, COPD accounted for 75.6% of the country's disability-adjusted life years (DALY) related to chronic respiratory diseases. The expense of managing COPD is also quite excessive. COPD not only results in a significant financial burden but also lowers quality of life, reduces productivity, increases hospital admissions, and increases the risk of early death. The prevalence of COPD among males and females in India is 11.4% and 7.4%, respectively.[7] Smoking and occupational-based factors were common reasons behind COPD among men. In the case of women exposure to biomass fuels such as wood smoke and dung regularly was the major factor. In India factors like under-diagnosis, late diagnosis, limited access to healthcare facilities especially in rural areas, and poor adherence to treatment plans result in poor management of COPD.[8] Better knowledge about the early signs and symptoms of COPD as well as its general existence may facilitate early diagnosis and prompt treatment.

Pharmaceutical treatments for COPD, such as corticosteroids and bronchodilators, are undoubtedly helpful, but inexpensive drugs are scarce. Many people in India may find it difficult to afford COPD treatment, especially given the chronic nature of the illness. The anticipated economic loss resulting from COPD in India in 2011 was ₹350 billion, which exceeded the ₹251 billion entire budget of the Ministry of Health and Family Welfare of India for the 2010–2011 fiscal year.[8] Medications and drugs account for a large amount of Indian households' out-of-pocket (OOP) health spending and have emerged as a major cause of catastrophic costs for both inpatient (hospitalization) and outpatient treatments.[9] The Department of Pharmaceuticals, Government of India, introduced the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) or Jan Aushadhi scheme (“people's medicine" in Hindi) in 2008 in response to the financial burden that marketed branded drugs placed on underprivileged populations. This public health initiative aims to provide generic medications at reasonable costs in specially designated pharmacies known as "Jan Aushadhi Kendra’s." There are 9998 Janaushadhi Kendras functional across the country. Their product list comprises 1800 drugs and 285 surgical items.[10] Here the costs of scheduled and nonscheduled drugs are regulated by the National Pharmaceutical Pricing Authority under the Government of India. The Janaushadhi Kendras are scheduled to grow to 25,000 outlets by 2028–2029, with the goal of guaranteeing its presence in 745 districts across the nation.[11]

In this paper, we examine whether medications provided under the Jan Aushadhi scheme are more affordable than those sold under brand names. A cost-minimization analysis (CMA) will be performed to identify the least expensive medication or combination of medications. A substantial variation in generic and branded costs was observed in studies conducted on anti-cancer drugs. This study will compare the most expensive and least expensive branded drugs on the market with the cost of Jan Aushadhi medications used to treat COPD.

## METHODS

The cost of generic formulations of drugs used in the treatment of COPD, at jan Aushadhi Kendra was identified. and listed from the Product portfolio given in the PMBJP.[10] This was then compared with the prices of branded counterparts available in the market. Given that multiple companies manufacture or sell pharmaceuticals with similar formulations at different price points in India, we opted to select both the highest-priced and lowest-priced formulations for each drug to ensure a comprehensive comparison.[11]

The cost of branded formulations available in the Indian Market was collected from the current index of medical specialties (CIMS) July to October edition 2023 and Medguideindia.com.[12] The price of each unit in the form of tablets, injections, or syrups was calculated.

To ensure data consistency, drugs not found on those sites were not included in the study. This approach made sure that the only verified and readily available pricing data served as the foundation for our study. The cost of drugs used for the study was considered in Indian Rupees (1 US Dollar=83.91 INR).

For formulations available in different weights, a standard weight was selected for consistency in the study. We calculated the cost difference, cost variation, and cost ratio for each formulation. To determine the cost difference, the price of the Jan Aushadhi medication was subtracted from the prices of its highest-priced and lowest-priced counterparts.

The cost ratio is the ratio of the highest-priced drug available in the market to the lowest-priced formulation of the same, it was calculated using the formula,

$$Cost\ ratio = \frac{Maximum\ cost}{Minimum\ cost}$$

Cost variation is the difference between the cost of Jan Aushadhi medication when compared to the highest-priced and lowest-priced drugs available in the market. It can be calculated using the formula,

$$Cost\ variation = \frac{Maximum\ cost - Minimum\ cost}{Minimum\ cost} \times 100$$

The data obtained were analyzed using Microsoft Excel 2015 and reported as summaries and percentages. As this study is a secondary analysis, no ethical clearance was obtained. However, to address ethical concerns, the brand names and manufacturers of the formulations for each drug have not been disclosed in any part of the study.

## RESULTS

A total of 11 drugs and their different formulations (31) were included in the study for analysis which comprised anti-inflammatory drugs, inhaled bronchodilators, methyl xanthines, anticholinergics, and corticosteroids. We analyzed single units as well as combinations. There was a wide variation in price observed among the drugs of different brands. In Table 1, the results of the cost of single units, cost difference, cost ratio, and cost variation of COPD medications are denoted.

**Table 1: Results of the comparison in cost of single units, cost difference, cost ratio, and cost variation of COPD medications.**

| S. no | Generic name with dose and formulation | Maximum price per unit (branded drugs) | Minimum price per unit (branded drugs) | Jan Aushadi drugs | Cost ratio (highest-priced and lowest priced) | Cost difference (highest-priced and lowest priced) | Cost variance (highest-priced and lowest priced) |
|---|---|---|---|---|---|---|---|
| **1** | Acebrophylline 200 mg (sustained release) and montelukast 10 mg tablets | 250 | 135 | 55.00 | 4.54 and 2.45 | 195 and 80 | 354.54 and 145.45 |
| | Acebrophylline capsules 100 mg | 120 | 50 | 22.00 | 5.45 and 2.27 | 98 and 28 | 445.45 and 127.27 |
| | Acebrophylline sustained release tablets 200 mg | 189 | 99.9 | 30.00 | 6.3 and 3.33 | 159 and 69.9 | 530 and 233 |
| **2** | Doxofylline (sustained-release) 400 mg and montelukast 10 mg tablets | 169.25 | 62.86 | 65.00 | 2.60 and 0.96 | 104.25 and -2.14 | 160.38 and -3.29 |
| | Doxofylline tablets IP 400 mg | 99 | 33 | 17.00 | 5.82 and 1.94 | 82 and 16 | 482.35 and 94.11 |
| **3** | Etophyllin 77 mg and theophylline 23 mg tablets | 10 | 2.9 | 5.00 | 2 and 0.58 | 5 and -2.1 | 100 and -42 |
| | Etophyllin 84.7 mg and theophylline 25.3 mg injection per 2 ml | 33.57 | 3.94 | 2.00 | 16.78 and 1.97 | 31.57 and 1.94 | 1578.5 and 97 |
| | Etophylline 231 mg and theophylline 69 mg prolonged release tablets IP | 29.35 | 25 | 14.30 | 2.05 and 1.74 | 15.05 and 10.7 | 105.24 and 74.82 |
| **4** | Fluticasone furoate nasal spray 27.5 mcg | 379.5 | 254.07 | 138.00 | 2.75 and 1.84 | 241.5 and 116.07 | 175 and 84.10 |
| **5** | Formoterol 6 mcg and budesonide 200 mcg rotacaps | 168.67 | 165.64 | 85.00 | 1.98 and 1.94 | 83.67 and 80.64 | 98.43 and 94.87 |
| | Formoterol 6 mcg and fluticasone propionate 250 mcg inhaler | 748 | 356 | 290.00 | 2.57 and 1.22 | 458 and 66 | 157.93 and 22.75 |
| | Formoterol fumarate 12 mcg and budesonide 400 mcg powder for inhalation IP | 315 | 239.90 | 100.00 | 3.15 and 2.39 | 215 and 139.9 | 215 and 139.9 |

Continued.

| S. no | Generic name with dose and formulation | Maximum price per unit (branded drugs) | Minimum price per unit (branded drugs) | Jan Aushadi drugs | Cost ratio (highest-priced and lowest priced) | Cost difference (highest-priced and lowest priced) | Cost variance (highest-priced and lowest priced) |
|---|---|---|---|---|---|---|---|
| | Formoterol fumarate 20 mcg and budesonide 0.5 mg respirator suspension | 66.22 | 40.1 | 15.00 | 4.14 and 2.67 | 51.22 and 25.1 | 341.46 and 167.33 |
| | Formoterol fumarate 20 mcg and budesonide 1 mg respirator suspension | 74.43 | 46.7 | 20.00 | 3.72 and 2.33 | 54.43 and 26.7 | 272.15 and 133.5 |
| **6** | Ipratropium bromide respirator solution 250 mcg | 42.67 | 31.13 | 28.00 | 1.52 and 1.11 | 14.67 and 3.13 | 52.39 and 11.17 |
| **7** | Levosalbutamol 1.25 mg and budesonide 1 mg respules | 61.98 | 47.8 | 25.00 | 2.47 and 1.92 | 36.98 and 22.8 | 147.9 and 91.2 |
| | Levosalbutamol inhaler 50 mcg | 212.8 | 82.9 | 83.00 | 2.56 and 0.99 | 129.8 and -0.1 | 156.38 and -0.12 |
| | Levosalbutamol syrup 1 mg per 5 ml | 26.64 | 22.5 | 12.00 | 2.22 and 1.87 | 14.64 and 10.5 | 122 and 87.5 |
| **8** | Salbutamol 100 mcg and ipratropium 20 mcg inhaler | 249 | 182.2 | 110.00 | 2.26 and 1.65 | 139 and 72.2 | 126.36 and 65.63 |
| | Salbutamol inhalation IP 100 mcg per puff | 142.51 | 74.75 | 50.00 | 2.85 and 1.49 | 92.51 and 24.75 | 185.02 and 49.5 |
| | Salbutamol syrup IP 2 mg per 5 ml | 16.8 | 15.85 | 10.00 | 1.68 and 1.58 | 6.8 and 5.85 | 68 and 58.5 |
| | Salbutamol tablets IP 2 mg | 1.79 | 1.35 | 1.00 | 1.79 and 1.35 | 0.79 and 0.35 | 79 and 35 |
| | Salbutamol tablets IP 4 mg | 49.73 | 30 | 2.00 | 24.86 and 15 | 47.73 and 28 | 2386.5 and 1400 |
| **9** | Salmeterol 25 mcg and fluticasone propionate 250 mcg inhaler IP | | | 250.00 | | | |
| | Salmeterol 50 mcg and fluticasone 250 mcg rotacaps | 360.8 | 302 | 120.00 | 3.00 and 2.51 | 240.8 and 182 | 200.66 and 151.66 |
| | Salmeterol 50 mcg and fluticasone propionate 100 mcg powder for inhalation IP | 217.25 | 176.5 | 75.00 | 2.89 and 2.35 | 142.25 and 101.5 | 189.66 and 135.33 |
| **10** | Theophylline tablets 400 mg | 53.5 | 25.1 | 25.00 | 2.14 and 1.00 | 28.5 and 0.1 | 114 and 0.4 |
| **11** | Tiotropium bromide 18 mcg and formoterol fumarate dihydrate 12 mcg rotacaps | 260.9 | 185 | 75.00 | 3.47 and 2.46 | 185.9 and 110 | 247.86 and 146.66 |
| | Tiotropium bromide inhalation 9 mcg per actuation | 598 | 515 | 220.00 | 2.71 and 2.34 | 378 and 295 | 171.81 and 134.09 |

Out of the selected drugs for COPD, the highest cost difference was observed in the combination drug of formoterol 6 mcg + fluticasone propionate 250 mcg inhaler (the maximum price for the branded drug was INR 748, the lowest-priced branded cost INR 356 and it was available for INR 290 in JAS. The CD was found high in the case of drugs like tiotropium bromide inhalation 9 mcg (INR 378), fluticasone furoate nasal spray 27.5 mcg (INR 241), formoterol fumarate 12 mcg and budesonide 400 mcg powder for inhalation (INR 215), levosalbutamol inhaler 50 mcg (INR 130). The last CD was observed in the case of theophylline 400 mg tablets where the lowest-priced branded drug cost 10 paise more than the Jan Aushadhi drug. There were cases when the JA drug was a bit costlier than the lowest-priced branded drug, for example, the combination of etophylline 77 mg and theophylline 23 mg tablets (the JA drug cost INR 5 and the lowest-priced branded drug was 2.90 INR), similar results were obtained in the case of doxofylline (sustained release) 400 mg and montelukast 10 mg tablets (Jan Aushadhi drug cost INR 65 on comparison with lowest-priced branded drug INR 62.90). Differences were minimal in the case of etophyllin 84.7 mg and theophylline 25.3 mg injection per 2 ml (INR

2) and ipratropium bromide respirator solution 250 mcg (INR 3.10).

Among all the drugs used for the treatment of COPD, the highest cost variance in percentage between highest-priced and Jan Aushadhi drugs was found in salbutamol 4 mg tablets (2386%), followed by etophyllin 84.7 mg and theophylline 25.3 mg injection per 2 ml (1578%), acebrophylline capsules 100 mg (445%). The least cost variance was observed in ipratropium bromide respiratory solution 250 mcg (52.3%).

While considering drugs used for the treatment of COPD, the highest cost variance in percentage between lowest-priced branded and Jan Aushadhi drugs was found in salbutamol 4 mg tablets (1400%) followed by acebrophylline sustained release tablets 200 mg (233%), and formoterol fumarate 20 mcg and budesonide 0.5 mg respirator suspension (167%). The least cost variance was observed in levosalbutamol inhaler 50 mcg (0.1%), followed by theophylline tablets 400 mg (0.4%) and doxofylline (sustained release) 400 mg and montelukast 10 mg tablets (3.1%).

On the calculation of the cost ratio between the highest-priced drug and Jan Aushadhi drug it was observed that the highest cost ratio was in the case of salbutamol 4 mg tablets (24.86), followed by etophyllin 84.7 mg and theophylline 25.3 mg injection (16.78) and the least cost ratio was ipratropium bromide respirator solution 250 mcg (1.52). CR analysis of lowest-priced branded drug to Jan Aushadhi derived results as salbutamol 4 mg tablets (15) as the highest cost ratio and etophyllin 77 mg and theophylline 23 mg tablets (0.58) as the least cost ratio.

Among methyl xanthines, on analysis of highest-priced drugs and Jan Aushadhi drugs, a combination of etophylline 84.7 mg and theophylline 25.3 mg injection had the highest cost variance (1578%) and cost ratio (16.78) and acebrophylline sustained release tablets 200 mg had the highest cost difference (INR 159). Analysis of lowest-priced brand and Jan Aushadhi drugs showed that doxofylline (sustained release) 400 mg and montelukast 10 mg tablets had the least cost variance (3.29%) and cost ratio (0.96), etophyllin 84.7 mg and theophylline 25.3 mg injection had the least cost difference (INR 1.94). Study on bronchodilators derived that, on analysis of highest-priced drugs and Jan Aushadhi drugs salbutamol tablets 4 mg has the highest cost variance (2386%) and cost ratio (24.86). Salmeterol 50 mcg and fluticasone 250 mcg rotacaps has the highest cost difference (INR 240). In the case of the lowest-priced brand and Jan Aushadhi drugs, levosalbutamol inhaler 50 mcg has the lowest CV (0.12%), CD (0.10) and CR (0.99). In the category of anticholinergics tiotropium bromide inhalation, 9 mcg had the highest CD (INR 378), CV (171%), and CR (2.71) and ipratropium bromide respirator solution 250 mcg had the lowest CD (INR 3.13), lowest CV (11.17 %) and lowest CR (1.11). Among the anti-inflammatory category, only theophylline was considered in the study. In comparison with Jan Aushadhi, CD is (28.5 in the highest-priced and 0.1 in lowest-priced), CR (2.14 in the highest-priced and 1 in lowest-priced) and in the case of CV (114% in the highest-priced and 0.4% in lowest-priced).

## DISCUSSION

Ensuring the accessibility of affordably priced drugs is critical to the well-being of individuals and communities worldwide. Affordability of drugs is essential to efficient healthcare systems and is pivotal in tackling public health issues. India's estimated OOPE is 52% of current health expenditures, compared to the global average of 18%.[13] Additionally, the biggest contributor to household OOP health payments among healthcare expenses is the purchase of drugs (60.6%), which drives over 3% of Indians into poverty annually. This indicates how households affected by illness must be provided with financial risk protection. Research undertaken globally indicates that significant cost reductions could be achieved by shifting private sector purchases from branded medications to more affordable generic alternatives.

India's People's medicine scheme (Jan Aushadhi) was introduced in 2008 by the Department of Pharmaceuticals, GOI to make quality generic medicine accessible. It was later redesigned and renamed as PMBJP in 2015. In our study, we compared the drugs available in Jan Aushadhi pharmacies with their branded counterparts. Our study revealed that the price of branded drugs prescribed for obstructive pulmonary conditions was higher than that of generic drugs purchased from Jan Aushadhi pharmacies. Similar results were observed in other studies.[14,15]

According to their research, there was a notable difference in price between branded medications and the generic versions that were supplied by Jan Aushadhi pharmacies. In the case of drugs that doxofylline 400 mg tablet and a combination of etophyllin 77 mg and theophylline 23 mg tablets, there were few branded drugs which were comparatively cheaper than Jan Aushadhi medications even though the difference is minimal. According to our estimates, the price difference between branded and generic medications in the treatment of COPD is between 10 and 1400%. In this study, we investigated drugs from several classes, such as methyl xanthines, bronchodilators, and anticholinergics, which were prescribed to treat COPD. Our research findings indicate that across all classes of drugs investigated, the costs associated with generic drugs in Jan Aushadhi centers were markedly lower than those associated with branded drugs.[16]

Several studies have demonstrated that generic medications have the desired quality and are just as effective as branded medications.[17,18] Furthermore, comparative studies have confirmed that switching to generics can save the cost of treatment by nearly 15%. The bulk of out-of-pocket expenses in India is related to medicines, so providing patient households with access to affordable generic medications would be a crucial

strategy to attain significant savings in healthcare costs. Patients' lack of knowledge about the quality and pricing of generic drugs is one of the biggest obstacles to encouraging their use. Although doctors in public health institutions frequently write prescriptions for generic drugs, those at private healthcare facilities rarely write the chemical or generic names of the drugs on the prescription slips.[19] Physicians should take the initiative to encourage the prescription of generic medications and improve patient education about the use of these medications. Physicians should be provided with a manual of comparable medicine pricing that includes the majority of the national brands and available Jan Aushadhi counterparts so that the prescription costs can be lowered. To promote the adoption of generic medications, substantial revisions are necessary in national pharmaceutical policies, and there should be an expansion Jan Aushadhi framework with inclusion of more life-saving medications. Encouraging the utilization of generic drug medications can help manage the financial strain of out-of-pocket expenditures and alleviate the burden on individuals with lower economic means.

## CONCLUSION

In India, COPD patients and their families face significant financial burdens due to high medications and pharmaceutical expenses, which have led to the escalation of catastrophic costs associated with both inpatient and outpatient treatments, making it a barrier for sections marginalized sections of society. The results of our research study show that the drugs available at Jan Aushadhi pharmacies are substantially less expensive than their branded counterparts, which increases the accessibility and affordability of COPD treatment in our country. Patients may have less financial burden as a result of this price difference, which may enhance treatment compliance and health outcomes in COPD. Furthermore, the availability of these affordable options at JA pharmacies supports the broader goal of equitable healthcare access, contributing directly to sustainable development goal 3, which ensures healthy lives and promotes well-being for all at all ages.

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