RESEARCH ARTICLE

A Comparative Study of Branded and Generic Drugs: Cost Analysis in Indian Scenario

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ABSTRACT

Rising medicine costs adversely affects the access to healthcare and the economic status of households. Branded medicines are priced significantly higher than their generic equivalents (identical therapeutic value), even after the patent expiry. With governments pushing for greater adoption of generics, price remains the critical factor.

Objective: To understand the status of research into the 'Pharmacoeconomics' of generic medicine and test the fundamental premise of unbranded generic drugs being cheaper than branded drugs by conducting a comprehensive cost analysis in the Indian situation.

Methods: A qualitative analysis of the top-cited Scopus-indexed research papers published since Covid 19 (2020) has been carried, to understand the status of research into the 'Pharmacoeconomics' of generics, using VOSviewer (version 1.6.10). Quantitative cost analysis of branded drugs against their 'cost-effective' unbranded counterparts (generics) has been performed using current prices of drugs (solo-formulations) across the top 5 therapeutic categories.

Results: The bibliometric analysis indicates a strong positive association between volume of research and the adoption of generic medicine in a country. Though the fundamental premise of unbranded generic drugs being cheaper has been validated by and large, the possibility of it being vitiated is not ruled out. Highest cost variation was found in cardiology, respiratory and anti-diabetic segments.

Conclusions: India needs to increase its research and cross linkages in the domain of generic medicine to increase awareness and thereby adoption of generic medicine. Special attention needs to be paid on improving the efficiency and quality of local generic manufacturing plants to ensure cost effectiveness of generics.

Keywords: Generic Drugs, Branded Drugs, Pharmacoeconomics, Jan Aushadi, Cost Analysis, Bibliometric Analysis

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INTRODUCTION

Price has always been a significant barrier for access to pharmaceutical products to the general public. Paying due cognisance to this reality, democratic governments around the world have promulgated drug pricing regulations, especially for essential life-saving medicines. As per World Health Organisation (WHO), 'essential medicines' are those medicines that are required for the priority healthcare needs of people. India publishes its 'National List of Essential Medicines' (NLEM), which is periodically revised with price ceiling for these medicines fixed in accordance to the Drugs (Price Control) Order, 2013. The NLEM, however, only regulates the prices of medicines listed, accounting for about 17% of India's pharmaceutical sales volume.[2] Thus, leaving the majority of pharmaceutical drugs to market forces for price determination. And rightly so, having adopted a mixed economic model with "less government more governance" approach, else would result in dis-incentivisation of industry in India. Notwithstanding, a study led by Harvard University has found that, cost of medicines accounts for the largest share for Indian households in out-of-pocket (OOP) expenditure on healthcare, accounting for 16-21% of household incomes.[3] As a percentage of OOP expenditure healthcare, cost of medicines accounts for 60.3% of out-patient care and 29.1% of in-patient care. With costs of medicines posing such a high economic burden on households, many have referred to such OOP healthcare expenses as 'catastrophic' as they are often push low-income and middle-income households into poverty.[4] A study by *Sirag et al.*, found a high degree of correlation between government expenditure on healthcare and reduction in OOP spending on healthcare and poverty.[5] Various studies have also found that reducing the OOP health costs leads to better medication adherence outcomes among patients.[6] Thus, overall we see a twin benefit, in terms of better health outcomes and reduction in poverty levels in the population, by increasing government health expenditures. India's public healthcare expenditure has reached 2.1% of its GDP in the financial year 2022-23 (FY23), up from 1.6% in FY21.[7] However, according to estimates, India would be requiring to increase its public healthcare expenditure to 4-5% of its GDP for achievement of Sustainable Development Goal 3: 'Good health and well-being for all at all ages'.[8] Set with in this context is the argument for greater adoption of generic medicine in the country, as they provide effective cost saving in healthcare

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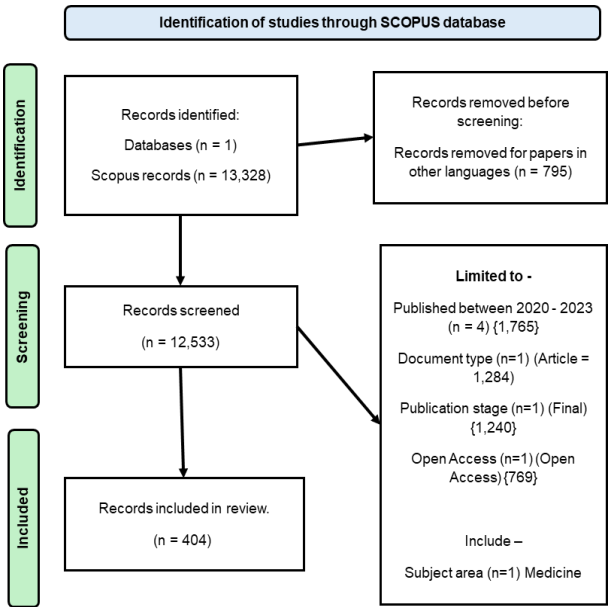

Figure 1: Flow diagram of the number of Publications of the identified research area.

expenditure for governments as well as patients, given that they are lower in price compared to their branded equivalents.[9] All this without compromising on the quality and therapeutic efficacy of the medicine. Pharmaceutical companies are granted patents i.e., exclusive marketing rights (EMRs), for drug molecules discovered by them for 20 years from date of discovery, to provide them an economic incentive and enable them to recover their investments in the research and development (R&D) of the innovator drug and subsequent marketing and promotional costs. During this patent period, other pharmaceutical companies are not allowed to manufacture the drug with the same composition. The drugs manufactured with the same composition by other pharmaceutical companies after this patent period are known as generic medicines and as such cost lesser than the innovator branded drugs, since they do not incur the R&D and marketing costs as the innovator pharma company does. WHO defines generic medicine as 'a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after expiry date of the patent or other exclusive rights'.[10] Moreover, generic medicine is undifferentiated from its corresponding innovator branded medicine in terms of its intended use, therapeutic efficacy, safety, quality, strength, route of administration, and hence can be called its pharmaceutical equivalent. Although, it is generally acknowledged, that some pharma companies do market their innovator drug product as a generic equivalent, with a different brand name, with the primary intention of maintaining market share,[11] the term 'generic' or 'generics' will be used in this paper to indicate a medication that is being marketed as a bioequivalent therapeutic agent that has not been developed by the innovator pharma company. In normal parlance, the term 'generic' when used to describe household articles gives an indication that the article is less effective or cheap or a duplicate article. This understanding however in the case of generic medicines does not hold good. Generic medicines, as mentioned above, are identical to their corresponding innovator branded counterparts, having the same active pharmaceutical ingredients (APIs) – the substance responsible for the drug's primary effect. They are expected to show the property of bioavailability and bioequivalence with their branded counterpart, i.e., the same rate and extent of absorption of the drug into the bloodstream. They differ only in the use of excipients - inactive ingredients of the drug. Excipients are inert

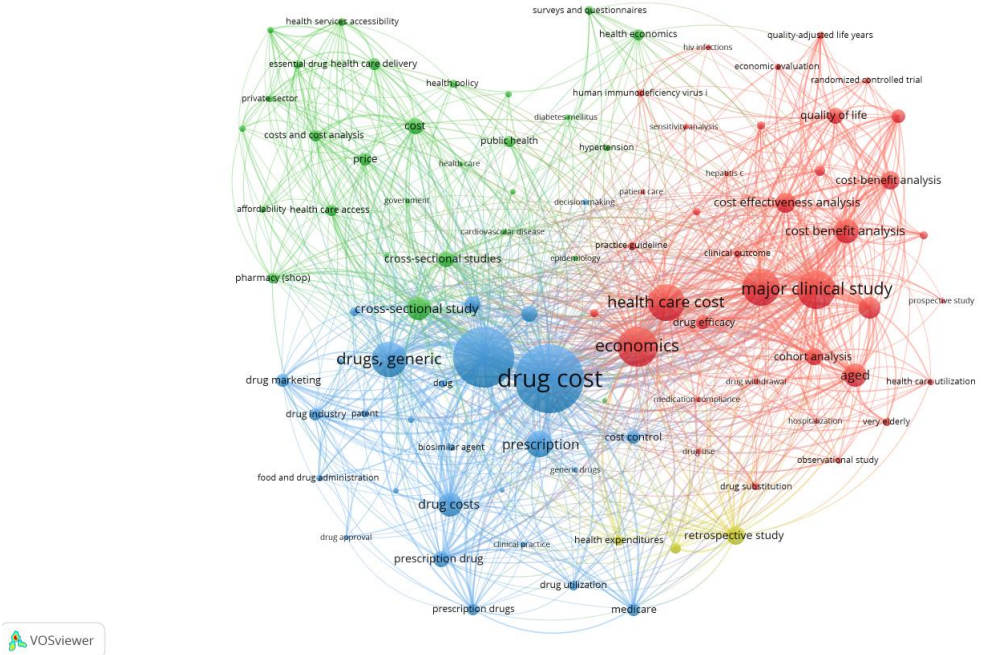

Figure 2: Network map of all the identified keywords

substances in therapeutics and function as fillers, preservatives, emulsifying agents etc., to support the process of the API.[12] In-addition to the direct benefit of healthcare cost reduction, generics also plays an indirect role in lowering the overall prices of branded generic equivalents through the introduction of price competition. In whole of the European Union (EU), entrance of generic medicines drove down the prices of off-patented medicines by 61%.[13]

Generics - Indian Scenario

India is hailed as the 'Pharmacy of the World', due to its high quality and efficient production of medicines for the world at affordable costs. It ranks 3rd by pharmaceutical production volume and 14th by pharmaceutical sales value globally.[14] 60% of global vaccine demand and 40-90% of WHO vaccine demand is fulfilled by the Indian pharmaceutical industry. More than a third of the generic medicines in USA and a fourth of United Kingdom's requirement of generics is catered to by Indian pharmaceutical companies. India is also home to more than 500 active pharmaceutical ingredients (API) manufacturers accounting for 8% of the global API market. It accounts for one-fifth of the global generic medicine supply, with manufacturing 60,000+ different generic brands spanning 60 odd therapeutic categories.[15] Among the greatest success stories in medicine, at the world stage, has been in the improved access to affordable medicines for HIV and AIDS treatment from India. Various studies and reports have brought out the growing prevalence of chronic non-communicable diseases (NCDs) like diabetes, chronic obstructive pulmonary diseases (COPD), hypertension, hyperlipidemia, hypothyroidism etc., owing to sedentary lifestyle choices among the people and rapid urbanisation taking place in the country. Added to this trend, a report published by Motilal Oswal Financial Services Limited (MOFSL) last year noted that, among Asian countries, India had witnessed the highest medical inflation (14%), followed by China (12%), Indonesia and Vietnam (both

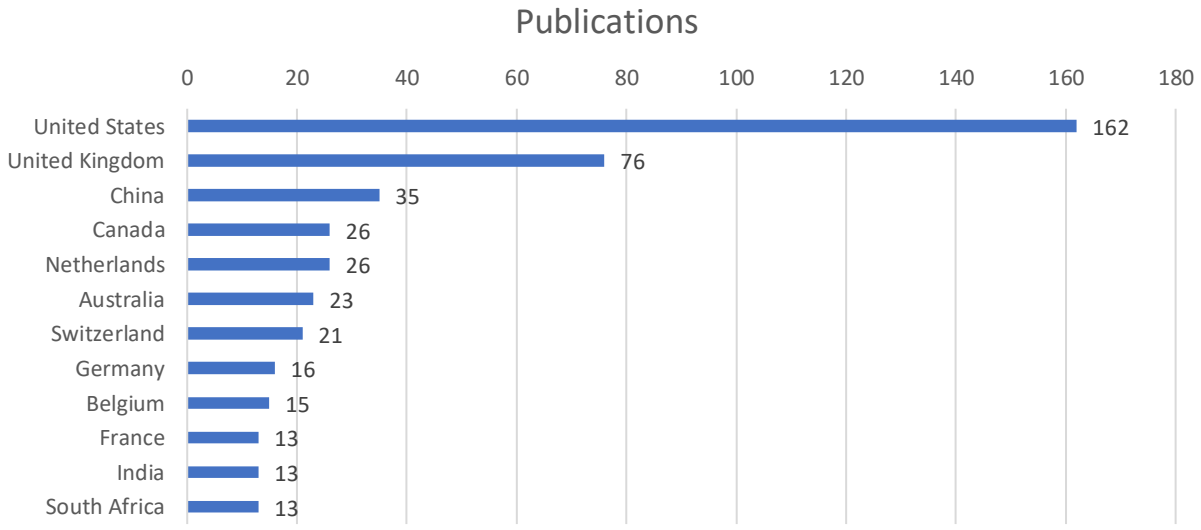

Figure 3: Bar graph of top countries in terms of publications

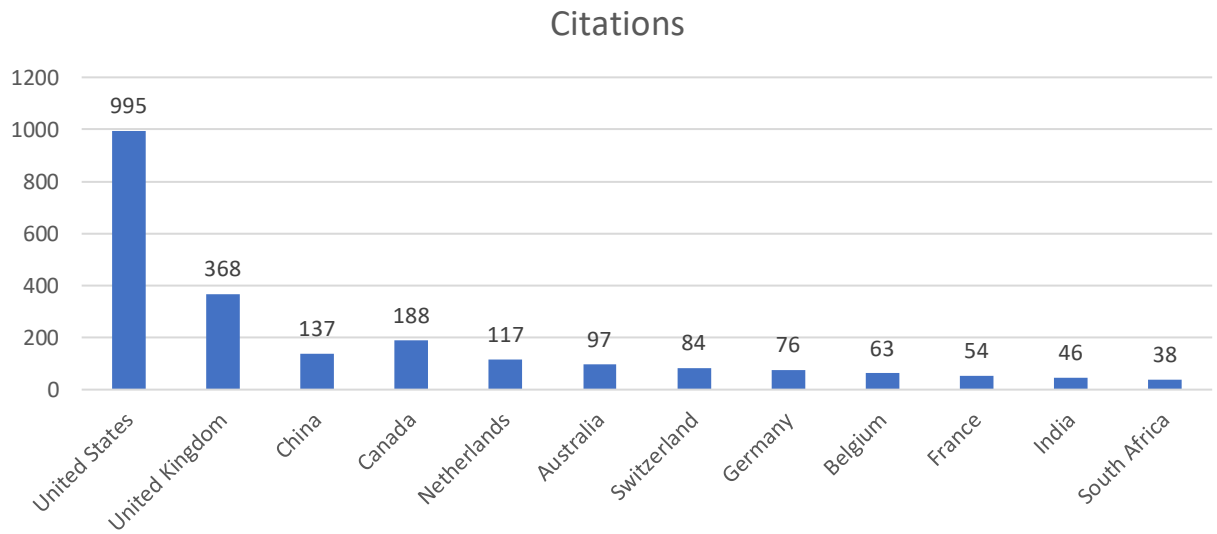

Figure 4: Bar graph of top countries in terms of citations

with 10%).[16] With an expanding aging population added to this potent mix of factors, it makes a prime case for greater adoption of cost-effective generic medicines in India. Taking due cognisance of this fact, Indian government launched the Jan Aushadhi Scheme, which is now known as Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP), on 1st Dec 2008. It is being implemented by Pharmaceuticals & Medical Devices Bureau of India (PMBI), under the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers. Touted as the world's largest pharma retail chain, 9303 Janaushadi Kendras (Jan Aushadi Stores) are operational, with a product basket of over 1800 medicines and 285 surgical items,[17] thus ensuring access to quality and cost-effective medicines to all sections of the population, especially the socio-economically backward. Recognizing this opportunity, especially in the past 5 years, we have seen many private generic medicine start-ups sprouting on the Indian pharmaceutical retail landscape – StayHappi Pharmacy, Zeno Health, Genericplus Pharmacy, medkart Pharmacy, Dawaa Dost and so on. Among them, Dava India Generic Pharmacy (2017), a brand of Zota Healthcare Ltd, has emerged as India's largest private generic pharmacy chain with more than 650 outlets across 25 states.[18] In 2022, the Generic

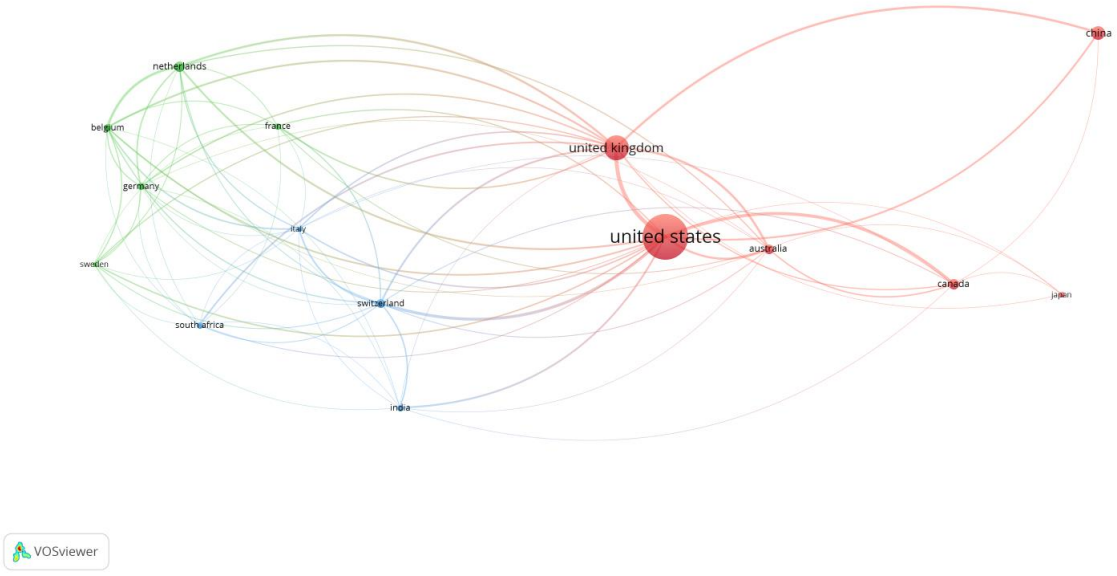

Figure 5: Network of countries of origin of publications

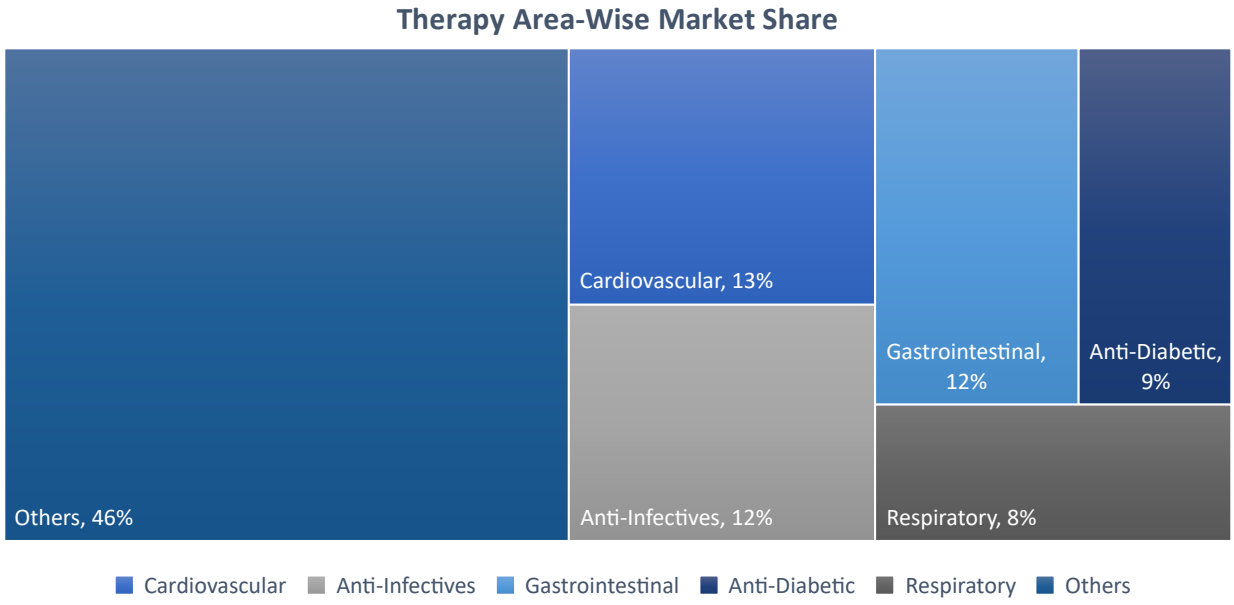

Figure 6: Therapeutic area-wise market share of the Indian Pharma Market
Source: ICRA, Indian Pharmaceutical Industry, March 2023.

Table 1: Cost comparison of medicines for cardiovascular therapeutic segment

Cardiovascular Drug Composition	Package Unit	JAS MRP (Rs)	No. of Brands	High-est Brand MRP (Rs)	Low-est Brand MRP (Rs)	Brand Avg Price (Rs)	Std Dev of Brands	% Difference		
								Hig-hest	Average	Lowest
Telmisartan 20mg	10 tabs	6.73	116	99.00	17.10	38.60	10.03	1371%	474%	154%
Atorvastatin 10mg	10 tabs	5.60	93	80.00	17.50	51.41	10.18	1329%	818%	213%
Ramipril 5mg	10 tabs	9.68	74	105.00	24.40	70.83	17.69	985%	632%	152%
Febuxostat 40mg	10 tabs	16.60	120	98.40	69.00	113.25	26.83	1095%	582%	316%
Rosuvastatin 20mg	10 tabs	27.34	81	469.00	79.00	236.28	81.61	1615%	764%	189%

Table 2: Cost comparison of medicines for anti-infectives therapeutic segment

Anti-Infectives Composition	Package Unit	JAS Medicine MRP (Rs)	No. of Brands	Highest Brand MRP (Rs)	Lowest Brand MRP (Rs)	Brand Avg Price (Rs)	Std Dev of Brands	% Difference		
								Hig-hest	Ave-rage	Lowest
Ampicillin 500mg Inj	1 vial	7.20	53	30.75	4.24	14.97	6.04	327%	108%	-41%
Ciprofloxacin 250mg	10 tabs	8.10	57	38.00	10.00	25.44	6.63	369%	214%	23%
Levofloxacin 500mg	10 tabs	26.80	53	182.98	42.50	82.46	17.93	583%	208%	59%
Azithromycin 500mg	10 tabs	80.60	145	390.00	107.32	224.05	28.98	384%	178%	33%
Clindamycin 300mg	10 Cap	54.77	75	360.00	133.33	238.06	38.98	557%	335%	143%

drug market in India stood at US$ 24.53 billion.[19] It is estimated to grow at a compound annual growth rate (CAGR) of 6.97% during 2023-2028 taking into account the increasing government initiatives and the booming pharmaceutical industry, which has grown nearly 10 times in the last 2 decades.[20] Presently, 100% foreign investment is allowed in the pharmaceutical sector. Among the government schemes, the Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), the Pharmaceutical Promotion and Development Scheme (PPDS) and the recently launched Production Linked Incentive (PLI) Scheme under 'Make in India' Policy are driving growth in the sector.[21] All these developments in the country lend pertinence for further research studies into generic medicine, especially from the cost perspective, as it has been identified as an important barrier for adoption. Though many price comparison studies have been done in the domain, recent studies in India, especially after COVID 19, have been little to none. This paper brings out this fact through a bibliometric analysis of research publications globally, while also uncovering underlying themes of these publications. In the latter part of the paper, a price comparison between branded medicines and their unbranded generic therapeutic counterparts across various therapeutic segments has been carried out. This has been done to verify or confirm the findings of previous studies with current price points (as of June 2023).

METHODOLOGY

Two-fold research methodology has been adopted for this study. The first part deals with the qualitative study, where a bibliometric analysis of the current research papers published in Scopus had been performed in the domain of generic medicine. The second part is a quantitative study dealing with the price comparisons of the top branded drugs and generic equivalents across various therapeutic categories. Substantial amount of literature has been published incorporating various perspectives and dealing with different facets of generic medicine. Analysing these studies was felt to be pertinent in order to gain a comprehensive overview as well as uncover underlying themes and patterns. With various bibliometric analysis tools gaining wide popularity as an aid for qualitative analysis in gaining deeper insights of the available literature, we have chosen VOSviewer (version 1.6.10) to conduct the bibliometric analysis in this study. The articles were arranged in descending order based on the number of citations, with priority given to more recently published articles in the case of a tie in citation count. In June 2023, a comprehensive electronic search was carried out to locate the published articles on generic medicines and savings, using Scopus database. The search in question included original articles published only in the English language. The search terms were identified based on extensive literature review in the research area. The search term used to identify the matching article publications included 'generic

Table 3: Cost comparison of medicines for gastrointestinal therapeutic segment

Gastroenterology Drug Composition	Package Unit	JAS Medicine MRP (Rs)	No. of Brands	Highest Brand MRP (Rs)	Lowest Brand MRP (Rs)	Brand Avg Price (Rs)	Std Dev of Brands	% Difference		
								High-est	Av-erage	Low-est
Cyproheptadine 4mg	10 tabs	2.25	59	40.86	3.12	16.69	8.82	1716%	642%	39%
Omeprazole 20mg	10 tabs	6.50	58	61.20	6.67	30.14	8.40	842%	364%	3%
Itopride 50mg	10 tabs	35.50	30	167.39	38.00	71.26	28.74	372%	101%	7%
Levosulpiride 25mg	10 tabs	9.50	52	129.00	41.00	77.23	20.41	1258%	713%	332%
Pantoprazole 40mg	10 tabs	11.00	76	157.00	26.00	89.20	27.58	1327%	711%	136%

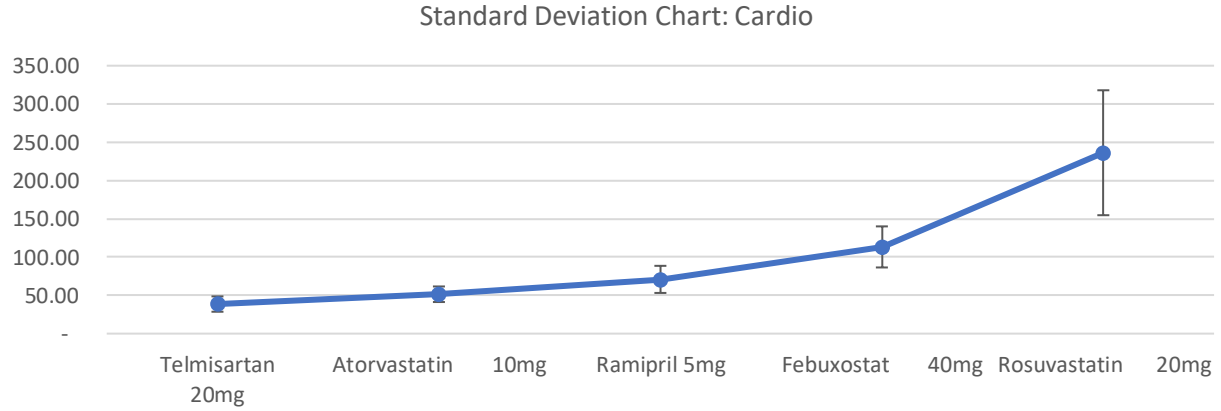

Figure 7: Standard deviation price chart for branded cardiovascular medicines

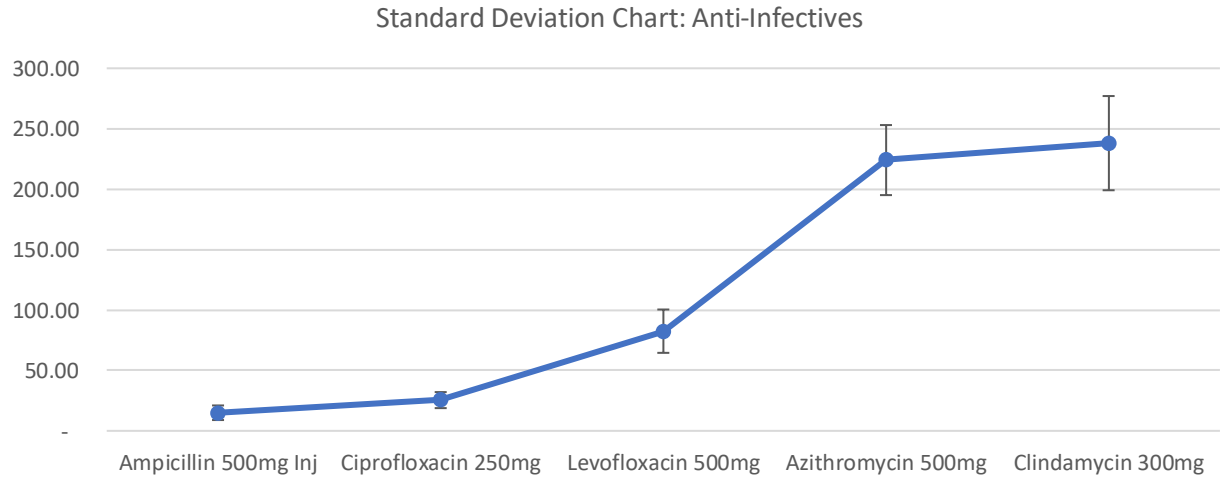

Figure 8: Standard deviation price chart for branded anti-infective medicines

medicine' OR 'generic drug' OR 'generics' occurring along with 'generics' OR 'generic medicine' AND along with 'savings' OR 'price' OR 'healthcare costs' OR 'drug costs' OR 'economics', were used as the keyword search queries in the title, abstract and keywords. The details of the research publications that matched the criteria - language, year of publication, journal, title, author, co-authors, affiliation, keywords and abstract, which were converted into CSV format. The retrieval took place on 15th June, 2023.

Search Query

```
TITLE-ABS-KEY((("generics" OR "generic medicine" OR "generic drugs") AND ("savings" OR "healthcare costs" OR "drug costs" OR "price" OR "economics"))) AND ( LIMIT-TO ( LANGUAGE,"English" ) ) AND ( LIMIT-TO
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( PUBYEAR,2020) OR LIMIT-TO (
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PUBYEAR,2022) OR LIMIT-TO (
PUBYEAR,2023) )  AND ( LIMIT-TO (
DOCTYPE,"ar" ) )  AND ( LIMIT-TO (
PUBSTAGE,"final" ) )  AND ( LIMIT-TO (
OA,"all" ) )  AND ( LIMIT-TO (
SUBJAREA,"MEDI" ) )
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Figure 1 gives the flow diagram that explains the screening process followed to arrive at the results. In the recent past, 'Pharmacoeconomics' as separate field of study has been gaining traction globally, across health systems. Hitherto, Health Economics used standard tools, that were available to economists in general, to inform health policy makers. This was overshadowed with the movement of Pharmacoeconomics which focused on 'evidence-based' approach to medicine; thus, requiring medicines, diagnoses and therapies to establish themselves and prove their effectiveness, both therapeutically and economically.[22] Pharmacoeconomics is defined as a branch of health economics that critically analyses pharmaceutical products and services from the standpoint of maximizing the value for patients, governments, and society on the whole, especially since health-related resources are scarce and access is limited.[23] Pharmacoeconomics deploys tools to conduct analysis of health cost from the perspective of

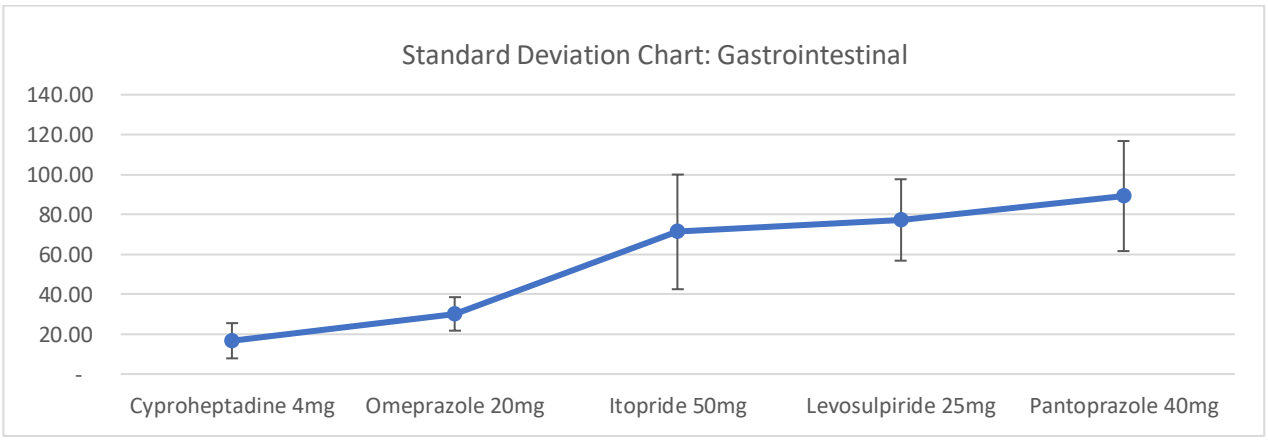

Figure 9: Standard deviation price chart for branded gastrointestinal medicines

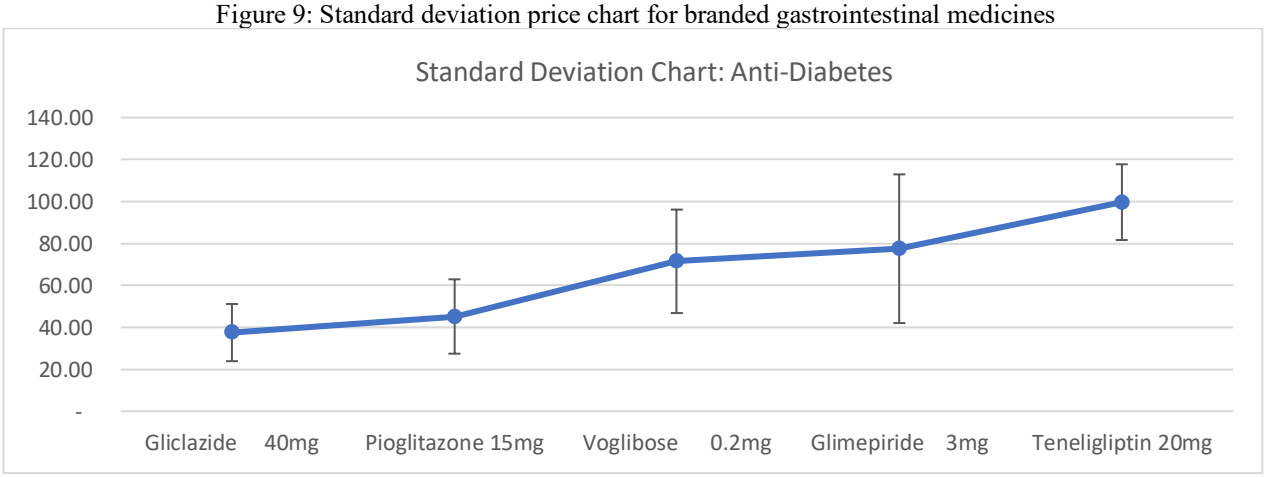

Figure 10: Standard deviation price chart for branded anti-diabetic medicines

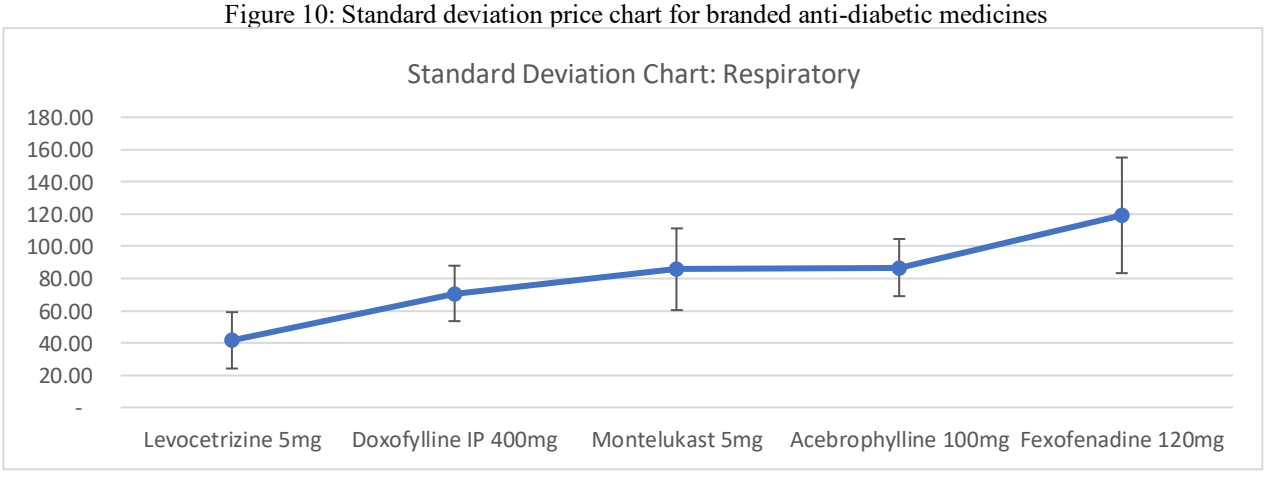

Figure 11: Standard deviation price chart for branded anti-diabetic medicines

Table 4: Cost comparison of medicines for anti-diabetic therapeutic segment

Drug Composition	Package Unit	JAS Medicine MRP (Rs)	No. of Brands	Highest Brand MRP (Rs)	Lowest Brand MRP (Rs)	Brand Avg Price (Rs)	Std Dev of Brands	% Difference		
								Highest	Average	Lowest
Gliclazide 40mg	10 tabs	11.93	55	87.00	17.00	37.48	13.63	629%	214%	42%
Pioglitazone 15mg	10 tabs	6.75	50	90.00	17.00	45.15	17.72	1233%	569%	152%
Voglibose 0.2mg	10 tabs	10.00	72	142.27	24.90	71.45	24.66	1323%	615%	149%
Glimepiride 3mg	10 tabs	5.00	59	170.50	9.00	77.46	35.43	3310%	1449%	80%
Teneligliptin 20mg	10 tabs	49.50	89	139.00	45.00	99.64	18.06	181%	101%	-9%

Table 5: Cost comparison of medicines for respiratory therapeutic segment

Pulmonary Drug Composition	Package Unit	JAS Medicine MRP (Rs)	No. of Brands	Highest Brand MRP (Rs)	Lowest Brand MRP (Rs)	Brand Avg Price (Rs)	Std Dev of Brands	% Difference		
								Highest	Average	Lowest
Levocetrizine 5mg	10 tabs	4.10	89	97.00	10.95	41.61	17.48	2266%	915%	167%
Doxofylline IP 400mg	10 tabs	9.50	75	115.00	31.50	70.72	17.21	1111%	644%	232%
Montelukast 5mg	10 tabs	11.25	35	147.00	33.90	85.71	25.37	1207%	662%	201%
Acebrophylline 100mg	10 caps	17.10	114	159.00	46.00	86.75	17.75	830%	407%	169%
Fexofenadine 120mg	10 tabs	21.00	50	223.80	53.00	119.16	35.86	966%	467%	152%

minimization, effectiveness, impact, utility, benefit and consequence. As such this study tries bring out a cost comparison between branded medicines and their unbranded generic therapeutic counterparts, in the top 5 therapeutic segments by sales volume in India. Again, within these therapeutic segments, top 5 solo formulation medicines, have been identified for cost analysis. Price data (MRP) has been taken from Jan Aushadi Price Book for unbranded generics, while the branded drug prices have been sourced from netmeds.com and 1mg.com with location of Hyderabad. The medicine price of the generic version has been compared against the brand with highest price, average price and the lowest price, while bringing out respective cost savings in the categories. Extensive efforts have been made to cover maximum number of branded medicines in circulation. A minimum of 50 brands have been considered to arrive at the average price of branded drug formulation (except for only 2 drug formulations for which minimum 30 brands have considered due to scarcity in drug manufacturers). Standard deviation in the respective drug prices has also been computed to give a better understanding of the price characteristics. While doing so, this paper has tried to analyse the basic premise of generic medicines of being cost effective than branded drugs of the same formulation.

Bibliometric Analysis

Keywords that occurred for more than 15 times in the Scopus database were empanelled in the final analysis. Of the 4513 keywords, 115 of them met the threshold. Few keywords that were not indicative of the research area were removed, such as human, male, female, questionnaire, etc. The keywords that appeared most were ‘drug cost’ (occurrence - 207, total link strength - 2103), ‘generic drug’ (occurrence – 182, total link strength - 1792), and ‘economics’ (occurrences – 120, total link strength - 1365) which are strongly connected. Below (Figure 2) is the network visualisation map of the identified key words. The identified keywords are forming four clusters with 95 items in total, including 3599 links with total link strength of 19647. Cluster 1 with 37 items includes keywords like cost-benefit analysis, drug efficacy, drug safety and treatment outcomes. Cluster 2 with 28 items includes keywords such as affordability, health economics and diseases like cardiovascular, diabetes and hypertension. Cluster 3 which includes 27 items has keywords like healthcare policy, insurance and drug prescription. Cluster 4 has only 3 items having to do with the type of studies like longitudinal and cross-sectional.

Among the 94 countries who have published research papers in the area of study, 15 countries meet the threshold of 10 documents. Upon running the diagnostics, we find 3 clusters forming with 75 links and a total link strength of 241. Most of the publications were found to be from the United States of America (document 162, citations 995, total link strength 86), followed by United Kingdom (document 76, citations 368, total link strength 77) and next

by China (document 35, citations 137, total link strength 15). India shows links with 10 countries (document 13, citations 46 and a link strength of 18). Figure 5 gives the network map of the publications by country of origin, while the below bar charts show the country wise publications (Figure 3) and citations (Figure 4). Based on the above data we can infer that there is certainly scope for increasing India's research emphasis with respect to generic medicine to bring out the cost benefit of the same, thus increasing awareness among the populace and mainstreaming its adoption, especially in the post-covid scenario. This can be corroborated by the fact that countries with highest research publications and citations (US and UK) in the domain, also have high proportions of generic medicine among prescription. Generic medicine accounts for 90% of all prescriptions in the US and 85% of all prescriptions in the UK.[24] Interestingly, these are the same countries that also show strong research linkages in the domain with other countries. International research linkages bring out a host of benefits, from exchange of knowledge and perspectives to cross-cultural learnings. It perhaps finds its greatest application in the field of evidence-based policy making as it enables comparative analysis, policy evaluation and identifying best practices.[25] This can help in framing and implementation of appropriate policies for mainstreaming of generic medicine in India. While regulations for 'generic prescription' have been issued by the Indian Medical Council (Professional Conduct, Etiquette and Ethics 2022), their effective implementation has considerable room for improvement. At the same time, policy on 'generic substitution' both from the physician's side and the pharmacist's side, has not been dealt. On such aspects, research linkages with other countries, especially developing countries, can bring diverse experiences and lessons learnt cases to bear on better adoption outcomes.

Cost Analysis

As per the ICRA March 2023 report on Indian Pharmaceutical Industry, the Indian pharmaceutical market is pegged at about Rs. 1.8 lakh crores in revenue terms, with a year-on-year growth of 7.7% in FY2023, mainly supported by price escalations.[26] Based on the data from the same report, the Indian Pharmaceutical market share therapeutic area-wise has been brought out in figure 6. The top 5 therapeutic areas– Cardiovascular, Anti-infectives, Gastrointestinal, Anti-diabetic and Respiratory diseases – account for ~54% of the Indian pharmaceutical market in revenue terms. The remaining minority share is accounted by therapeutic areas like analgesics, dermatology, neuro/CNS, gynaecology and vitamins/minerals/nutrients. Within each of these top 5 therapeutic areas, again top 5 solo drug formulations (not including combination formulas) have been identified and cost analysis for the same has been carried out between branded medicines and their unbranded generic equivalents. This would mean that, drug combinations like teneligliptin + glimepiride would not be considered and teneligliptin and glimepiride anti-diabetic drugs would be considered separately with respective dosages. This has been done so as to bring about equity in drug price comparisons. Generic drug price has been taken from the latest Jan Aushadi Scheme (JAS) Price book and has been compared to the highest, average and lowest branded drug price, to compute respective savings.[27-29] Various brand formulations have been covered extensively to include maximum number of brands in the market. Standard deviation of the brand prices has also been computed and displayed graphically to provide insights into the market price stabilization of respective therapeutic drug formulations. The above-mentioned analysis has been presented therapeutic area-wise below, from Table 1 to 4 respectively. Please note that brand names of the highest and lowest priced generic medicines haven't been furnished, though available with the authors, as it might prejudice the audience in favour / against of the same. It is clear from table 1 that the unbranded generic medicines available in the Jan Aushadi Stores are significantly cost effective in comparison to their branded versions. Among the therapeutic segments, drugs for cardiovascular diseases show the highest average cost saving (in excess of 650%). The standard deviation chart (Figure 7) shows near market stabilization in cardiovascular drug prices among majority brands, with the exception of Rosuvastatin 20mg. It is welcome to note that for such drugs JAS is providing maximum cost benefit resulting in much needed relief for patients. The premise of unbranded generic drugs being cost effective than branded equivalents is called into question especially in the lower price segment of branded anti-infective formulations. With pharmacists and online platforms offering attractive discounts on MRPs of branded drugs, there is high likelihood of branded drugs being lesser in price than JAS medicines. In the case of Ampicillin 500mg injection, we see this phenomenon even without the application of MRP discounts (Table 2). This could be a cause for concern. The JAS even in this segment is providing maximum savings for formulations with higher standard deviation in prices. The cost analysis of the gastrointestinal therapeutic segment reveals interesting trends (Table 3). Though on average the cost savings through JAS medicines is higher (more than 500%), they parallelly run a definite risk of being higher in cost than their branded counterparts in lower price category, as we see in the case of Omeprazole 20mg and Itopride 50mg. The standard deviation chart for the drug segment (Figure 9) shows wide price variations. Here we would wish to highlight the case of Itopride 50mg which shows high standard deviation and has very few manufacturers. Such instances create situations where people are pushed into buying high priced medicines. Such cases should be avoided in the interest of consumer choice. The anti-diabetic therapeutic segment assumes special importance in the light of India accounting for 17% of world diabetes burden and being dubbed as the 'Diabetes Capital of the World' with over 100 million diabetics and rising. With this market showing wide variation in prices (Figure 10) for most branded drugs, JAS is providing generics for fraction of the cost thus improving access to affordable medicine for this population. This therapeutic segment shows the maximum price difference between branded and generic drugs in the higher price drug category, while also exhibiting the tendency of costing higher than few branded medicines (as in the case of Teneligliptin 20mg). The

respiratory / pulmonary therapeutic segment shows the second highest cost savings (across highest, average and lowest categories) after the cardiology segment (Table 5). This should be a welcome development especially in the post COVID scenario, with many recovering from both cardio and pulmonary morbidities. With still some way for market price stabilisation (Figure 11), JAS is providing the much needed price relief. From the above tables we can conclude that, across the mentioned therapeutic categories, unbranded generic medicines are cheaper than their branded counterparts. The percentage difference (cost variation) indicated however could be lower, as maximum retail price (MRP) has been considered as cost of the branded drugs. Generally, the pharmacists offer discounts ranging from 5-20% on this MRP at the time of sale, which in the case of e-pharmacies can go up to even 40%.[30] As such there is a definite possibility of the branded medicines, especially in the lower price category, to be cheaper than the unbranded generics. This has been seen in the case of Teneligliptin 20mg and Ampicillin 500mg Injection. Theoretically, there could be two possible reasons for this occurrence – higher retail margins or inefficient local manufacturing[14]. Assuming retail margins in JAS not to be extensive, it leaves inefficient production of local generic manufacturers as the primary reason for unbranded generics to cost higher, as the high production cost is passed down to the medicine buyers. Focussing on local manufacturing also brings up the issue of 'quality', which has been called into question after a spate of drug contamination cases. This calls for a relook into quality control measures and government regulation with respect to generic medicine manufacturing – a probable future area of research.

CONCLUSION

With the direct benefits of drug cost reduction and the indirect benefits of improving medication adherence and bettering health comes, for both patients and governments; albeit offering comparable quality and therapeutic efficiency with innovator counterparts, the case for greater adoption of generic medicine has never stood more bolstered. It parallelly calls for stepping up efforts to spread awareness among the public and promotion among prescribers in favour of generic medicines. 'Cost' (drug) and 'drug safety' has shown high linkage in cluster 1 of the network map of keywords (Figure 2) indicating that these aspects need to be further researched in the Indian context and the same emphasized in communications for awareness. More research on various aspects of generic medicine is sought, as the bibliometric study has brought out the fact that India, though being the 'pharmacy of the world', has a very low share in terms of publications and citations on the global level. The same can be said about improving research linkages with other countries, as the outcomes of such studies can significantly plug the gaps in generic prescription and generic substitution in the country. Also, evident for the keyword clusters formed in the network maps, more studies on Pharmacoeconomics of generic medicine in India need to be undertaken, which will add to its mainstreaming. Though the fundamental premise of unbranded generic drugs being cheaper than branded drugs has been validated by and large, the possibility of it being vitiated is not ruled out. This aberration has been pointed out by other studies as well. Particular attention has to be shown on improving efficiency and quality of local generic manufacturing plants in such cases, else the very purpose of offering affordable generic medicines to the vulnerable sections, will be diluted to that extent. The endeavour has to be to maximize the cost effectiveness on medicines for diseases that carry the highest burden. This has been attested to by the findings of this paper, where the highest cost variation in the favour of generic medicines has been found in the cardiology, respiratory and anti-diabetic segments. Within these segments, of special importance are the drug formulations that show wide price variations and whose market price stabilisation is not yet achieved. In such cases, unbranded generics should be cost effective without exception, as such conditions could push patients into purchasing high priced medicines. Future studies could deal with multi-drug formulations in each therapeutic category as they are gaining popularity as a more effective approach for drug delivery. Exploring the indirect costs of generic medicine in another research area that could be explored, while adopting a holistic stakeholder approach – government, pharma companies, physicians, pharmacists, drug manufacturing plants and patients – to provide deeper insights into the field.

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