



# REVIEW OF RESEARCH

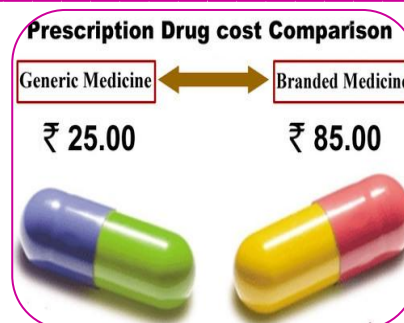
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## "GENERIC MEDICINES (COST EFFECTIVE MEDICINES): NEW ERA IN INDIAN PHARMACEUTICAL MARKET"

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### ABSTRACT :

*Medicines has become the integral part of the life, due to various ailments have been increasing across the globe. To control / treat the disease, doctors prescribe medication which may be a brand or generic. Usage of Generic Medicines in developed country has reached to the peak level on the contrary India has very low awareness & usage. Generic Medicines are very economical as compare to Branded medicines.*

**KEY WORDS:** *Generic Medicines, Chronic Illness, Cost Effective Medicines, Awareness.*

### INTRODUCTION:

The research throws light on the facts of Generic Medicine, its usage / awareness in developed countries vis-à-vis India. It also clears Myths related to Generic medicines & also shows how patients can save their hard earned money if they opt for Generic Medicines over Brand with illustrative example.

### NEED & SIGNIFICANCE:

Pharma companies incur lots of promotional expenses which is directly proportional to the MRP of the medicines. Prices of the medicines have been increasing year over year. Patient need is Cost effective medicines in case of Chronic Illness, where in they need to take medicines for life long. If Indian Govt. compels doctors to prescribe medicines in generic form or runs campaign to increase the patient awareness / education to opt for generic medicines, then patients can save their hard earned money.

### Objective:

**To study the scope of Generic Medicines w.r.t. India**

### Hypothesis:

Patients need cost effective medicines (Generic Medicines) over highly priced branded medicines.

### Research Methodology:

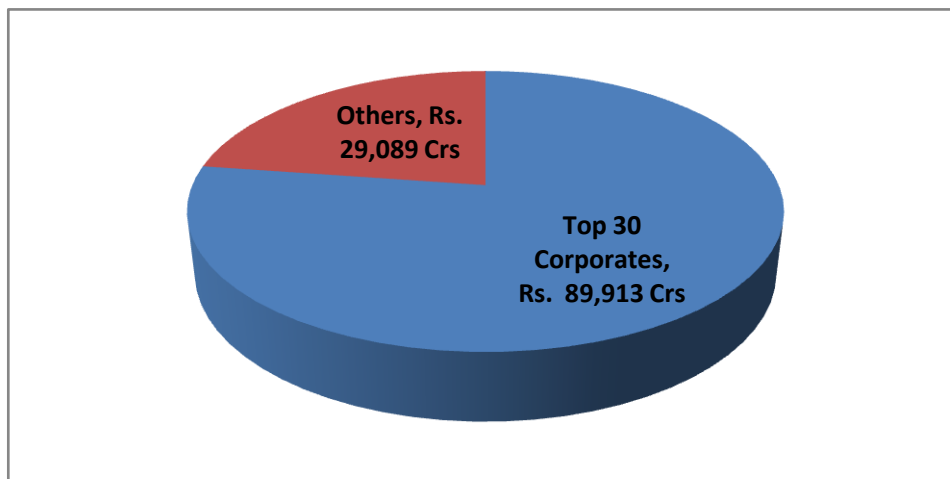
Researcher has collected secondary data by browsing various websites & portals as well as referred to various Journals

### Increased Expenses on Medicines for Chronic Illness

Prevalence of Various diseases / ailments are been increasing in India, this directly affects the pocket of the patients (Costumers) since they need to buy medicines. Further, various promotional expenses directly impacts the prices of the brands which lead to HIGH COST therapy.

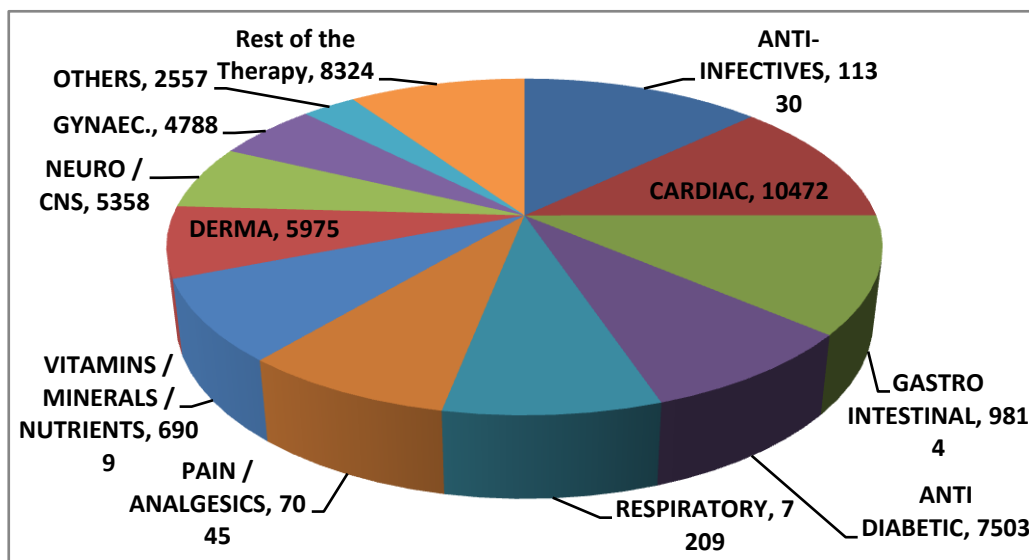
### Indian Pharmaceutical Market:

The Indian Pharma Market Size is **Rs.1,19,002Cr** with the growth of 10.5%. In such market top 30 companies contributes to almost 75% of the market. That mean Pharma Giants have Big Equity in the doctor's mind which results in the Prescription support to them & there by increased sales of the medicines.



### Dia: Top 30 Corporates contributes to 75% of Indian Pharmaceutical Market Share

There are various ailments such as Infections, Pain, Cough, Cold, Hypertension, Diabetes, Urological disorders, Neurological disorders, Gynecological problems, Skin diseases etc. These are classified into two such as Acute Illness & Chronic Illness. Acute Illness is usually last for 5-7 days & Chronic is for lone term. There are various medicines available in the market to treat these diseases and are classified majorly in 2 categories Acute Therapy & Chronic Therapy. While if we see the therapeutic segment it comprise of medicines used to treat various ailments such as antibiotics, pain, Cough, Cold, Hypertension, Diabetes, Urological disorders, Neurological disorders, Gynecological problems, Skin diseases etc. 70% of the medicines are been used to treat Chronic Illnesses (1)



### Dia: More than 70% of medicines are been used to treat Chronic diseases.

### **Global View - Pharmaceutical Market.**

The Global Pharmaceutical Industry Revenue in 2017 was 1,105 bn USD.(2)The Global Pharmaceutical Industry Revenue is forecasted to reach an estimated 1.2 trn USD by 2024 (3). If we see the penetration of Generic Medicines, 67% of Prescription are been prescribed in Canada is of Generics. The US FDA confirms that in the year 2015 7 out of 10 prescriptions were prescribed in generics, which as increased to 8 out of 10 in 2016 & by 2018 it has reached to 9 out of 10 prescriptions were prescribed in generics in the United States. (4) When we see Indian Pharma Industry at Global level, India ranks 10<sup>th</sup> in terms of Value & Ranks 3<sup>rd</sup> in terms of Volume. Further, it is been estimated that IPM shall reach 55 Billion USD by 2020.(5)

### **India Health Care System:**

According to WHO there has to be 2.5 doctors & 2.5 nurses per 1000 persons, however unfortunately, there are only 0.7 doctors and 1.5 nurses per 1000 persons. Indian needs 1.5 millionsdoctors & 2.4 millions nurses to match the global average. The shortage of Qualified Medical Professionals is one of the key challenges faced by Indian Health Care Industry. (6) Looking into these facts there is more responsibility on the shoulders of Para Medics or Pharmacists.

While looking at Manufacturing Facilities in India, according to research done by IBEF in March'2014, Indian Pharmaceuticals Manufacturing facilities registered with the Unites States Food & Drug Administration (USFDA) stood 523, which is highest for any country outside USA. This tells that Manufacturing Facilities in India are at par with the Global Standards.(7)

Medical Council of India which is the regulatory body on Indian Medical Associations already had Code of Ethics Regulation published in 2002, as per chapter 1, code of ethics 1.5 – **"Every Physician as for as possible prescribe drug with the generic names, he/ she shall ensure that there is rational prescription & usage of drugs."**(8) This code of ethics had loop holes – the word "as far as possible" hence doctors haven't supported / written Generic Medicines till July'2016. On 28<sup>th</sup> July' Chemical &Fertiliser minister Mr. Ananth Kumar requested Health Ministry to change the guidelines & make Generic prescription mandatory, the said request is accepted & approved immediately. As a result of this Medical Council of India has published new guideline in the Gazette Notification on 21<sup>st</sup> Sept'2016. The new guide lines says – **"Every Physician Should prescribe drug with the generic name legibly & preferably in capital letters. And he/ she shall ensure that there is rational prescription & usage of drugs."**(9)

Across the globe two type of medicines are available, Branded Medicines (Innovator Pharma Company, Patented, Additional Expenses on R &D, Sales Promotion, High Cost) Generic Medicines (Off Patent, No Additional Expenses, Very Cost Effective)

**Branded Medicines :**A drug company develops new drugs as brand-name drugs under patent protection which involves huge expenses on research & development further expenses on promotion. This in turn protects the investment in the drug's development by giving the drug company the sole right to manufacture and sell the brand-name drug while the patent is in effect. All this leads to huge cost which usually taken from patient's pocket.

When patents or other periods of exclusivity expire, other manufacturers can submit an abbreviated new drug application (ANDA) to the FDA for approval to market a generic version of the brand-name drug.

Although generic drugs are chemically identical to their branded counterparts, they are typically sold at a cheaper price than the brand-name drug because the drug has not been developed from scratch, and the costs to bring the drug to market are less.

**Generic Medicines :** A generic drug is a drug that is exactly the same as the brand-name drug, but can only be produced after the brand-name drug's patent has expired.

A generic drug is the same as a brand-name drug in:

- dosage
- safety
- strength
- quality
- the way it works
- the way it is taken
- the way it should be used

The below table shows the Price Comparison of Cost of Branded Medicines Vs Generic Medicines:

Ailments	Medicines (Molecule)	Cost (Per 10 Tab)	
		Branded Medicines	Generic Medicines
Blood Pressure	Telmisartan 40 mg	Rs. 93.00	Rs.23.00
Acidity	Rabeprazole 20 mg + Domperidone 30 mg	Rs. 115.00	Rs.25.00
Diabetes	Voglibose 0.3 mg	Rs. 113.00	Rs. 30.00
Diabetes	Metformin 500 mg	Rs. 15.00	Rs. 6.00
Ortho Disorder	Calcium 500 mg + Vit. D3 250 mg	Rs. 92.00	Rs.15.00
Urological Disorder	Tamsulosin 0.4 mg	Rs. 137.00	Rs.30.00

In India, the biggest challenge at the patient's level is Huge Expense on High Cost Branded Medicines especially to treat Chronic Illness (the treatment requires life-long). Actually the need of the patient is Cost Effective Medicines and the comparison chart clearly shows that there Generic Medicines are Very Cost Effective.

As a common process, patient goes to the doctor for the check up when he/she is not keeping well. Doctor/ Physician check up&prescribe the medicines depending upon the disease type (acute/chronic). In case of acute illness, medication is been given for 5-7 days. And in Chronic illness, doctor recommends the medicines to be taken for lifelong which controls the illness. Now such patient comes out from the clinic or hospital & goes to the pharmacy to buy the medicines & most of the time he/she purchase the medicines WITHOUT any discounts. In other words, he/she usually don't get any discounts on the medicines. When the patient is going for medication for acute illness (usually for 5-7 days) he/she doesn't not worry about cost/value of the bill. But, when patient is suffering with chronic illness, he/she needs to buy medicines for Life-long, in such situation they think about HOW CAN I Save my Money??

If we see the Comparison Chart (Branded Vs Generic Medicines), it clearly states that generic medicines are Cost Effective. When a doctor has prescribed a Medicines, which is been promoted by a Pharma Company being various cost involved such as Sales Promotion, Advertising, Marketing and R & D Expenses, the cost or the price is too high. At the same time, if the patent of same molecule is over / expire it is available in the Generic form would be a Much Economical, because Generic Medicines are a as Safe and As Effective as Branded medicines.

Unfortunately, there is Lack of Awareness, Lack of Knowledge & Lack of Trust about Generic Medicines in India. The usual Myths & Facts about Generic Medicines (10,11) are as follows:

#### **Myth # 1. Generic Medicines are Not Safe as Branded Drug**

Fact : Generics use the same ingredients, and work in the same way in the body have the same risk-benefit profile. A generic medicine works in the same way and provides the same clinical benefit as its brand-name version. This standard applies to all FDA-approved generic medicines.

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### **Myth # 2. Generic Medicines are Not as Potent as Branded Drug**

**Fact :** Generic drugs have the same quality, strength, purity and stability which is FDA's requirement, hence their potency remains same.

### **Myth # 3. Generic medicines take long time to act in the body.**

**Fact :** The generic drug delivers the same amount of active ingredient in the same time as the original drug.

### **Myth # 4. Generic medicines cost less because they are inferior to brand name drugs.**

**Fact :** Generic drugs are less expensive because generic manufacturers don't have the investment costs of the developer of a new drug. New drugs are developed under patent protection. The patent protects the investment—including research, development, marketing, and promotion--by giving the company the sole right to sell the drug while it is in effect. As patents near expiration, other manufacturers can apply to the FDA to sell generic versions. Because those manufacturers don't have the same development costs, they can sell their product at substantial discounts. Also, once generic drugs are approved, there is greater competition, which keeps the price down. Today, almost half of all prescriptions are filled with generic drug.

### **Myth # 5. Branded drugs are made in modern manufacturing facilities, and generics are often made in sub-standard facilities**

**Fact :** Both brand-name and generic drug facilities must meet the same standards of good manufacturing practices. Sub-standard facilities are not permitted by the FDA.

Now days, both Central and State Government are encouraging the usage of Generic Medicines since these are equally efficacious as that of Branded Medicines and that too at a lower price. This is certainly going to help the common man of this country to save his hard earned money on the cost of therapy.

Central government is promoting usage of Generic Medicines and also started Chain of retail pharmacy called "Jan-Aushadhi Kendra" in various states of India. Hon. Prime Minister Mr. Narendra Modi himself is a brand ambassador of Jan-Aushadhi PariYojana.(12) Further, lots of players are also emerging into this forthcoming market. One of the company is successfully spreading its wing is Generilife Private Limited in Maharashtra thru its chain of retail pharmacy called SwastAushadhi Kendra". **Generilife Swast Aushadhi Kendra**® is also committed to "Increase the awareness of generic medicines" in the society through various activities. Generilife, aspire to encourage youths to come forward and become Entrepreneur with a social cause of selling Generic Medicines at substantially discounted price to the needy patients through their own franchise of "**Swast Aushadhi Kendra**". (13)

### **CONCLUSION :**

Patients can save their hard earned money if they go for generic medicines rather than branded medicines. They should discuss it with their physicians / or discuss with Pharmacist. India has big scope where there is less awareness about generic to the common man.

### **SUGGESTIONS :**

State government should aggressively promote usage of generic medicines. Should run campaigns to increase patient awareness / education at City / Village level. Further Government should monitor adherence to the new MCI guidelines strictly. FDA to be more vigilant in terms of quality assurance & should encourage more and more manufacturers to add production of Generic medicines as well.

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