# A REVIEW ON GENERIC MEDICINES

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## Abstract: -

Generic medications are the copies of branded medications whose patents have expired. Branded medications are innovative creations of pharmaceutical companies. They share similar active ingredients, dosage form, quality, and other factors. People are frequently confused by the various packaging and prices. Due to a lack of understanding and awareness, generics are the subject of numerous myths in India. Their increased concerns over the quality and safety of generic medications, doctors typically do not recommend them. The lower revenues on generic drug sales and less consumer demand, pharmacists no longer distribute generic medications. The Jan Aushadhi scheme was introduced by the government to offer everyone access to generics medications at reasonable prices. There are many obstacles in the way of accessing generic medications in India.

**Keywords:-** Generic medications, Branded Medications, Pharmaceutical Companies, Active Ingredients, Awareness.

# INTRODUCTION

**Generic medicines**:

According to FDA, "A drug product that is comparable to branded product, which has same dosage form, strength, administration route, quality, performance, characteristics, and use. It is a copy of branded drugs whose patent has expired, which has no longer exclusive rights to produce and distribute medicines. [1]

**Branded Medications:**

It is the original drug that has been developed by pharmaceutical company. Every time a new drug is discovered, the inventor files for intellectual property protection. No one may currently manufacture this medicinal product without a patent holder's consent or a licence from one. Following a legal procedure involving the payment of a royalty, patents are transferrable. The first company to identify, create, and market a medicinal product is Innovator Company. [2] If a product can demonstrate bioequivalence with the innovator's drug, it can be made and marketed by anybody without the innovator's consent after the patent protection period expires typically 20 years unless otherwise specified. These goods are referred to as generics, and their producers are called generic manufacturers, as opposed to branded medicines produced by innovator firms. [3]

**Similarities Between Generic and Branded Medications:**

The same active substances must be present.

It must have the same dose form, and they must be of the same quality and effectiveness.

It must be given in the same route of administration.

Both generic and branded medications are safe.

The bioavailability is the same. [4]

**Difference Between Generic and Branded Medications:**

It must include other inactive substances.

Generic medications are cheaper than branded ones.

Generic and branded medications are different in shape, size, colour, and branding, they seem differently.

While generic drugs lack a patent on their manufacturing and distribution, branded drugs have exclusive patents to manufacturing and distribution for a fixed period of time. [5]

**Effectiveness of Generic Medications:**

In terms of active ingredients, generic medications are the same as their branded medications, but they may have different inactive components. When a medicine is being manufactured, inactive components are added for stability and preservation as well as to obtain a specific consistency, form, colour, or flavour. [6] These ingredients have no effect on therapeutic effect of the drug. The Food and Drug Administration approves generic medications on the basis of tests show their efficacy, safety, and purity. This implies that a branded medication and a generic medication can be used interchangeably. There is no proof that branded prescriptions are better than generic ones. [7]

The quality of generic medications is a major source of concern. The FDA thoroughly investigates all generic medications, including a review of the scientific data regarding the generic drug's components and effectiveness, to ensure quality, safety, and efficacy. The FDA also demands that a generic drug manufacturing facility follow same standards as of the manufacturing of branded medications. The FDA performs about 3,500 on-site inspections annually to make sure this requirement is being followed. [8]

**Advantages of Generic Medications:**

Cheaper prices- The main reason so many individuals purchase generic medications is because they are so much less expensive than branded medications. Generic medications merely need to reproduce what already exists, saving them the cost and enabling the price to remain cheap. Branded medications need extensive research and testing that takes a lot of time and money. [9]

Bioequivalent- In terms of biology, generic medications must follow to specific standards to ensure that the same quantity of the active component is consumed and absorbed into the body in the same manner as the branded medication.

FDA approved-**.** To make sure that generic medications are bioequivalent to brand-name medications, the FDA establishes strict rules and conducts research on them. [10]

Generic Drugs are Accessible to the Poor- The best method for reducing increased treatment costs for those with limited financial resources is to use FDA-approved generic medications. Generic medicines are equivalent to branded medicines that people can purchase from their nearby pharmacist. Generic medications are easily accessible to those with lower incomes and effectively treat symptoms and ailments in the same way as branded medications. [11]

Cost-Efficient for Healthcare Systems- Generic medications are frequently prescribed to patients by government-run healthcare facilities. The main justification for doing this is to cut back on extra expenses and help those in need without generating any trouble. Generic medications are accessible to medical service providers in administration as well as patients. By making generic drugs more affordable and available to the general public, the likelihood

that people will remain healthy increases. Patients are encouraged to have fewer future health concerns when medications are easy to acquire. [12]

Generic Drugs are easy to Manufacture- Branded medicine producers carry out the most fundamental and important research. Because of this, developing an identical duplicate of the pharmacological elements of a certain drug requires less expense for generic drug businesses. Following R&D is marketing a generic product. A producer can readily cut further costs because generic medications are not marketed. [13]

**Disadvantages of Generic Medications:**

Misconceptions and Doubts- Generic medications are produced for less money and are based on the branded medications patent's early research and development stages. People mistakenly believe that generic medications are less safe and less effective because they think they are produced in poor facilities.

Customers are hard to Convince- Even after selling these medicines at the lowest possible cost, the main problem facing generic medicine suppliers is customer approval. Customers can be difficult to find without promotion or advertising strategies. [14]

Contamination- Generic medications are commonly produced in factories in nations like India, China, or other places with low labour and overhead costs. Drug in the United States have occasionally been caused by the conditions at these factories contaminating the products. To be fair, though, there have been a few instances where brand-name drugs made in the US have experienced similar problems, but not quite as frequently. [15]

Oversights- Global factories may avoid strict FDA inspections, avoid having their procedures documented, and don't receive follow-up monitoring. A branded medications is usually only made by one manufacturer, but a generic medications may be made by several companies. Although the FDA demands on the bioequivalence of the active ingredient, there may occasionally be small differences in the medicines distribution method. [16]

Mixing up the pills- Generic medications frequently do not look as familiar or make it less clear what each pill is, but branded medications typically have a consistent branded appearance that patients can become used to and comfortable with. when a medication is repeated, if the drug is produced by a different generic manufacturer and has a different appearance, this may cause medication confusion, mistakes, or even patients who don't take the medication as directed. [17]

**Myths and Perception of Consumers about Generic Medications:**

If generics are safe or not?

Why are the generic medications less expensive?

If the price of the generic is low, it's possible that they're of worse quality.

Why do they appear different?

Do generic medications work as well as branded ones? [18]

**Jan Aushadhi Scheme launched in India:**

The Department of Pharmaceuticals and Central Pharma Public Sector have collaborated to launch the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) campaign, which aims to provide the general public with high-quality medications at reasonable costs through special stores known as "Pradhan Mantri Bhartiya Janaushadhi Kendra." These supply generic medications at cheaper price. These medications' potency is equivalent to that of branded medications offered on the open market. [19]

**Reason Scheme Being Not Successful:**

Excessive dependency on state government benefits.

Poor management supply chain.

Doctors not prescribing generic medications.

State governments start offering medications for free.

Lack of awareness of the general public. [20]

**Awareness and Communication to the Consumers will Increase the Consumption of Generic Medicines:**

A service that uses SMS to help citizens locate cheap generic equivalents.

Catalogs must be kept in stores for customer reference.

To learn about generic versions, there will also be activity on the web.

Workshops and seminars with doctors to spread the word and alert them to the protection of cheap generic medications. [21]

Use of social media, sufficient bravery in print and electronic media.

Education must be important to pharmacists. [22]

**Mandatory of Generic Medicines will Impact the Stakeholders:**

**Pharmaceutical companies-** Large pharmaceutical companies that have spent money on creating branded medications will suffer a loss**.** Smaller local companies can improve. maintaining the quality of generic drugs, especially for smaller companies.

**Doctors**- They will lose control over prescriptions. There is no need to keep records of branded names of pharmaceuticals. Changing their perceptions on generic drugs and educating and disciplining them will help consumers. [23]

**Pharmacists-** Pharmacist can aware the consumers about usage and therapeutic effects and side effects of generic medications .

**Patients**- Consumers may get substandard medicines in a cheaper price. Their awareness about generic medications will increase. [24]

The price difference between branded and generic medications can be as much as 85%, making it the most advantageous option. It has been demonstrated that less expensive generic pharmaceuticals improve patient health outcomes by increasing the likelihood that patients will take important prescriptions as prescribed by their doctors. Ask your doctor, if there is a generic version of the branded medication you are taking, or if there is a generic version of another drug in the same class. [25]

The distribution of generic medications in India is affected by a number of problems and obstacles, which has a negative impact on the country's consumption of pharmacy goods. The Jan Aushadhi Scheme centers that have been established by the Indian government and some Indian states in order to address some of these issues. This schemes aim to offer quality medications at reasonable costs to the general public all across the country. [26] If sponsors, healthcare providers, and regulators cooperate properly, then efficient usage of generic medications will lower medical costs and ensure that patients have access to safe treatments options. [27]

The quickly and effectively use of medications can ensure the effective treatment of many illnesses and help patients avoid or eliminate the need for expensive hospital care. Significantly, the use of generic medications has the chance to significantly lower expenses for patients and health care budgets while still effectively treating many of the illnesses of today. [28] Branded medications have definitely had a significant impact on how people use medications, but because generic medications are bioequivalent to their brand-name equivalents, they are considered both safe and cost-effective. [29]

Generic medications manufacturing is difficult since it it becoming agreements, patent laws, and no objection declarations from innovators, regulatory agencies, and authority figures. Additionally, it should be free of specific legal problems and capable of resolving any potential problems brought on by certain people. [30] From the raw ingredients used up until the drug reached the consumers on the market, the formulators faced numerous difficulties, including determining the drug's pricing. Discussions about the existing state of generics and the need for prospective adjustments, strategies, and important recommendations helped to resolve the legal issue. [31]

## DISSCUSION

India today has a significant market share on the worldwide scale, is recognised as the world's pharmacy, and is the largest provider of generic medications. India is the third-largest manufacturer of pharmaceuticals and manufactures of more than half of all vaccinations used worldwide. It provides 40% of the generic medicines demand in the US. India established

itself on the world stage due to its creatively engineered generic medications and active pharmaceutical ingredients (API). The country represents around 30% and 10% of the US generics market, which is worth between US$70 and US$80 billions.

Since the early 1960s and with the implementation of the Patents Act in 1970, the Indian government promoted increased medicine production by Indian businesses. Food and medication composition patents were eliminated by the Patents Act, and while process patents were retained, their duration was reduced to five to seven years from 20 years. Indian businesses addressed a market gap that resulted from the lack of patent protection in both the Indian and international markets by developing innovative low-cost medicine manufacturing techniques through reverse engineering. The Medical Council of India, 2002 code of ethics mandates that doctors only prescribe medications by their generic names. The largest pharmaceutical company in India, is Sun Pharmaceuticals, which is a global leader in the generic medicine market. Drugs manufactured by Indian generic companies were exported for $17.3 billion in the 2017–18 (April–March) financial year. From 1945 to 2017, only generic versions of medications were less than four years old were obliged to undergo bioequivalence tests. Since 2017, no matter what age, bioequivalence has been required for the approval of all generic medications.

## CONCLUSION

In India, it is a common perception that anything that is less expensive must not be of high quality. They also apply this assumption to generic medications, claiming that because of their low cost, they may be less effective and may worsen rather than improve their health. In order to improve the sales of generic medicines in India by increasing the commission on sale of generic drugs can raise the use of generics in India, we must expand the concept of community pharmacist in India, which plays a significant role in dispensing of medicines. The doctors and pharmacist's perception of generic medications can be improved by expanding the quality control department in India that tests and monitors the quality of generics.

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