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Generic drug development current scenario

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ABSTRACT
Generic drugs are a key part of today's healthcare systems. They provide cheaper options compared to brand-name drugs, but they are just as safe, effective, and high quality. These drugs work the same way as the original medicines because they contain the same active ingredients. They help lower the cost of healthcare and make medicines more accessible, especially in poorer countries. This paper looks at the worldwide situation of making generic drugs, how patent endings affect the market, and the different ways medicines are sold in various regions. It also covers the rules and regulations in the US, Europe, India, and the WHO's Prequalification Programme. The paper gives a close look at the situation in India, including government efforts like the Jan Aushadhi scheme and changes made to make generic drugs more available and trusted.
It also discusses some challenges, like making sure the drugs are of good quality, gaining trust from doctors, and following production rules. The paper ends with a comparison of prices between generic and branded drugs to show how much cheaper generics are.
Keywords :-Generic drugs , Brand-name drugs , Bioequivalence ,Patent expiration , Drug pricing ,Healthcare costs, Access to medicine , Pharmaceutical regulation , European Medicines Agency (EMA)

I. INTRODUCTION

Generic drugs have become an important part of today's healthcare system, giving patients more inexpensive and easy-to-treatment options. These drugs are copies of brand-nam drugs that have already been approved by regulatory bodies and have proved safe and effective to treat certain conditions. They provide the same quality, safety and effectiveness as original medicine, but at low cost, provide them to more people. Generic drugs have helped cut healthcare expenses, improve access to patients for patients, and to run healthcare systems more efficiently. According to the World Health Organization (WHO), generic drugs are medicines that are usually similar to brand-nam drugs and are marketed once of patent or other specificity rights for the original drug. The Drugs and Cosmetics Act, 1940 and Rules, 1945 do not clearly define what a drug generic or branded makes [1].

A generic drug is a type of medicine that is very similar to another medicine that has a well-known name or brand. It has the same effect on the body as the original medicine. Possible Generic drugs have the same main ingredient as a brand-name drug, but they may have different inactive ingredients. They also have to meet the same quality standards as brand-name drugs. Possible Generic drugs are usually the same as brand-name drugs in many ways, such as how much to take, how strong they are, how they are given, how safe they are, how well they work, and what they are used for. The law stops some medicines from looking the same as other medicines that are already sold. Brand-name companies use different colors, sizes, and shapes to sell more products. Possible - Generic medicines cost less than the original brand-name drugs for these reasons: .
1). No cost of identification and separation of new chemical unit (NCE), .
2). No cost of research and development, .
3). The cost of marketing a new drug is low because it is already approved by the authorities as safe and effective. Possible - A drug that is used for other drugs can be made: - when the patent is over; - Which has never been patented. - In those countries where a patent (s) is not used/not used; [2].

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II. GLOBAL MARKET LANDSCAPE OF GENERIC DRUG DEVELOPMENT

2.1. Market Size and Growth Trends

The global market for generic drugs has been growing steadily for the last ten years and is expected to keep growing because of things like drug patents running out, the lower cost of generic medicines, and government efforts to provide more affordable healthcare options.

2.2. Effects of Patent Expirations

A big reason for the growth in the generic drug market is when patents on high-profit brand drugs expir Between 2024 and 2027, patents on drugs that make over USD 236 billion in revenue are expected to end. This allows generic drug makers to take over more of the market. This is especially true for major drugs used to treat conditions like diabetes (such as GLP-1 receptor agonists), cancer, and heart diseases.

2.3. Regional Market Overview

A. North America

North America has the biggest share of the global generic drugs market, around 33%. The U. S. is the top country for using generic drugs. This is largely because of the FDA's ANDA process, which helps speed up the approval of new generic drugs. Supporting policies that help keep drug costs low, like Medicare incentives, and the growing number of biosimilars being approved are big reasons for this growth.

B. Asia-Pacific (APAC)

APAC is expected to grow the fastest, with a projected average growth rate of about 8% from 2025 to 2030.[3]

Countries like India, China, and South Korea are major producers of APIs and export a lot of generic drugs. India, often called the "pharmacy of the world," supplies 20% of the world's generic drugs and more than 40% of the U. S. 's generic drug needs.[4]

C. Europe

Europe has a mature generic drugs market. Countries such as Germany, the UK, and France use a lot of generic drugs because of their national health insurance systems. The EU has a centralized system that helps ensure consistent access to biosimilars and generic drugs across member states.

D. Latin America, Middle East, and Africa (LAMEA)

These regions have been slower to adopt generic drugs because of weak regulatory systems. But places like Brazil, Mexico, and South Africa are growing quickly. Governments in these regions are pushing for more local production to cut down on reliance on imported drugs.

2.4. Competitive Landscape

Big companies in the market include Teva Pharmaceuticals, Sandoz (part of Novartis), Sun Pharma, Dr. Reddy's Laboratories, Cipla, Lupin, Mylan (now part of Viatris), and AurobindoPharma. These companies are merging and acquiring others to expand their global reach and lower production costs. Investment in more complex generics, like inhalers, injectables, and eye treatments, along with biosimilars, is changing how competition works in the industry.

III. REGULATORY REQUIREMENTS IN GENERIC DRUG DEVELOPMENT

The development and approval of generic drugs are guided by strict regulations to make sure they are safe, work as well as the brand-name drugs, and are made to high quality standards. While the specific rules can vary a little from country to country, most have common requirements like showing that the generic drug is just as effective as the original, following good manufacturing practices, ensuring proper labeling, and keeping an eye on any side effects.

3.1 United States – USFDA (Food and Drug Administration)

In the US, generic drugs are approved using the Abbreviated New Drug Application (ANDA) process under the Hatch-Waxman Act of 1984.

Important things that must be shown are:

That the generic drug works the same way as the brand-name drug in the body That it has the same active ingredient, dosage form, strength, method of use, and labeling That it doesn't require full preclinical or clinical studies (except for proving bioequivalence) That it follows Current Good Manufacturing Practices (cGMP) that it has been tested for stability and impurities these applications are reviewed by the Office of Generic Drugs (OGD) within the Center for Drug Evaluation and Research (CDER) [5]

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3.2 Europe – European Medicines Agency (EMA)

In Europe, the EMA looks at generic drugs under Article 10 of Directive 2001/83/EC. This allows companies to submit a generic application without doing full clinical studies if:

The drug is bioequivalent to the original medicine It has the same active ingredients in the same amounts It comes in the same for the EMA also encourages the use of a Centralized Procedure for generics that want to be sold in many countries, or a Decentralized/MRP process for others [6].

3.3 India – Central Drugs Standard Control Organization (CDSCO)

In India, the Drugs and Cosmetics Act of 1940 sets the rules for approving generic drugs through the CDSCO. The requirements include:

Showing that the drug is bioequivalent for oral medicines doing stability tests based on ICH guidelines submitting a Common Technical Document (CTD) Getting approval from both CDSCO and State Licensing Authorities for making and selling the drug following Schedule M (which is about good manufacturing practices) [6]

3.4 WHO Prequalification Programme

For countries with less money, like Low- and Middle-Income Countries (LMICs), the WHO Prequalification Programme checks that generic drugs meet high standards for quality and effectiveness. The main parts of the process are:

Reviewing the full set of documents, including bioequivalence and GMP data

Inspecting where the drug is made and where any clinical studies were done

Focusing on important medicines, especially for treating HIV, TB, malaria, and reproductive health [7]

IV. INDIAN SCENARIO

Since India is the highest in the country of per capita out-off-pocket expenditure, such generics will save a lot of money that can be used for other health issues. [8] In all countries, the use of generic drugs in recent years has increased considerably. [9]

The rules that control generic drug approval are somewhat worldwide, with very little difference in developing countries, because it is not mandatory to undergo a study of bio -common (BE) to get approval for generics in this part of the world, and the gold standard for regulation in the field is the United States. [10]

In 2008, the Government of India began a new initiative "JaanAyadhi" (literally translated as medicine for people) through the Department of Pharmaceuticals, through the Department of Pharmaceuticals. The program provided the quality medicines available to poor people in the country at a reasonable and affordable price through the installation of retail shops with the help of the government. It has owned to set up a life of life, which is possible to sell pharmacies only to sell generic name drugs, giving preference to drug public sector undertakings. [11] As of March 15, 2018, 3200 Jan Ashadhi stores were working in more than 33 states/center areas across India. [12]

4.1 Quality Issues

Generic drugs are usually 30% -80% cheaper than promoter counterparts.This question is often raised, "Is the quality of generic drugs comparable for the quality and performance brand drugs?" Proponents of generic drugs claim that they are the same as brand or innovator drugs as effective. After this claim, in May 2016, the Drugs Technical Advisory Board of India of India considered amendment to Rule 65 (11A) of the Drugs and Cosmetics Act, 1940, so that pharmacists could overcome generic name drugs and/or equivalent brands against prescriptions in brand names. However, the skepticists have stated that the use of generic drugs may cause prolonged or even medical failure of the disease as a normal drug's bioavailability (BA) may not be good as the prescribed brand. [13]

4.2 Road Blocks

The government should ensure equal quality in all generics, and experts in the field of medicine say that the doctors will write them voluntarily and confidently.

One of the main causes of lack of confidence in normal drugs between doctors (and even patients) has been the absence of stringent regulatory requirements for the amount of drug in its general version and it permissible impurities. [14] But since 2016, clear-cut guidelines have been prepared, which suggests that the major pharmacocynetic parameters [maximum concentration (CMAX) and area under the curve] must have a 90% confidence of the generic-drug-to-brand-drag ratio.[15] BES (in Vivo) regulators required to ensure that the pharmaceutical equivalent reference product is equivalent to the standard reference product.

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V. PRICE COMPARISON OF GENERIC VS BRANDED DRUGS

Here are some examples that clarify the price difference between generic and brand drugs. For the price of Generic medicines, PMBJAK &Davaindia products were taken, compared to popular drugs Companies.

5.1. Its mandatory for writing prescriptions with generic names [16]

According to section 1.5 of the Indian Medical Council (Vocational Conduct, Etiquette and Ethics), 2002, every The doctor should prescribe medicines

- Generic names should be used in prescription
- Capital letters should be used to prescribe medicines in prescriptions
- To ensure rational prescription and use of medicine. Additionally, a circular of the Medical Council of India (MCI), It is said in 21.04.2017 that all registered medical doctors (RMPs) have been directed to comply with The above provision. Disciplinary action against a doctor can be taken by MCI or State Medical Councils Violation of the provision of the aforesaid rules. Complaints against violation of code of conduct for Doctors refer to the concerned State Medical Council (where doctor/medical practitioner) by MCI Registered to take necessary action). And according to the instructions of Tele-Medicine Guidelines 2020, Notified on May 22, 2020, all RMPs should use common names of drugs in big letters on leaflets Format.

5.2. Steps taken by the Government of India [16]

1. To promote and ensure the quality of generic drugs, the Ministry of Health and Family Welfare, Government of India has Towed as various regulatory measures
- With only appropriate/ general names, licensed officers will provide licenses for construction for sale for distribution of drugs.
- Now it is mandatory to give license grant for drug manufacture containing single active ingredients in the appropriate name. Only, according to amendment in drugs and cosmetics rules, 1945.
- According to the provision included in the rules, 1945, to submit the result of biodiversity studyn mandatory with the application for grant of manufacturing license in case of some drugs.
- According to a provision, the Central Government and the State Government's Drugs Inspector can conduct joint inspection manufacturing establishment.

5.3. Increased market share of generic drugs

According to landscape, developed to economics, with an increase in supplies of generic drugs, the price of these drugs It will be less i.e. opposite proportional. What is the reason? Behind the growing market share of generic there are medicines -

The expiry of the patent of the drug comes to the public domain and any pharmaceutical company construction

This increases the availability of drugs at low cost

- Large percentage of patients who have not been covered by health insurance/medical insurance
- Generic medicines / drugs are considered effective and safe as branded medicines because they are approved by regulatory bodies like FDA

VI. SALE OF GENERIC DRUGS IN THE COUNTRY

When compared with other countries, India has more facilities for making generic drugs than any other country except the United States, which is approved by the Food & Drug Administration (FDA). India has developed a strong and world-class generic drug manufacturing industry with major companies like Cipla, Ranbaxy, and Reddy's Laboratories. According to reports from the World Health Organization (WHO), about half of the world's population does not have proper health coverage. Nearly more than 95 million people live in poverty, and about 800 million people spend almost all their household income on medicines and medical bills, including in India. Right now, India is in a very important position in the pharmaceutical industry. It is considered the largest provider of generic medicines globally. In terms of volume, it provides about 20% of the global supply. It also supplies over 50% of the demand for various vaccines worldwide.

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Fig No. 01 Generic medicine

Exporting generic drugs is a key strength of India, which helps boost the country's economy. The generic medicine industry plays a vital role by focusing on offering, ensuring authenticity, making medicines affordable, and ensuring they are accessible. Patients are provided with quality medicines approved by WHO or FDA, but they often face challenges in ensuring the effectiveness of generic drugs compared to branded ones. The industry aims to educate the public about the authenticity and benefits of generic medicines. People only understand the value of these medicines when they learn about their advantages, which is a long-term process. To encourage the use of generic medicines, the Government of India started the PradhanMantriJanaushadhi Kendra (PMJK). This initiative benefits different groups of people across the country by helping them save money on medicines [17].

Figure 02 Logo of Pradhan Mantri Bahartiya Janaushadhi Pariyojana (PMBJP), an initiative of Government of India to provide quality and affordable medicines to all.

The campaign 'Prime Minister BharatiyaJanushadhiPariojana' (PMBJP) resumed in 2008 and again in 2015, for the great reason for the great reason i.e. to provide quality medicines at cheap prices for all (poor/needy people in all rural and urban areas. AIM Bureau of Pharma Public Sector Undertaking of India (BPPI) was established Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India to sell quality generics to the Government of India Medications across the country through dedicated outlets. (PMBJK)

Figure 03 Logo of PradhanMantriBhartiyaJanaushadhi Kendra (PMBJK), retail outlets under PradhanMantriBahartiyaJanaushadhiPariyojana (PMBJP) functioning all over India.

The categories for which medicines are available are antipiranational and analgesic/muscle rest, ant allergies, anticancer, antiinafacious, diuretic, central nervous system drugs working on the central nervous system, acting on drugs, drugs working on the cardiovascular system. endocrine glands, including steroids and immunospressant, medicines acting on eyes and ant, medicines acting on women breeding organs, acting on drugs gastrointestinal tract, medicines acting on the respiratory tract, skin acting drugs (Topical/local application), drugs acting on urinary organs, diabetes, vitamin-miners and drugs used in food Supplements, local/general anesthetics, solutions water and electrolyte disturbances and solutions to fix the vaccine. PMBJP provides self -employment and income opportunity to the pharmacist registered with a valid license and 10 square meters space anywhere in the country.

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Table No.02 Cardiovascular Drugs

Generic Name	Brand Name	Used For
Amlodipine	Norvasc	High blood pressure
Lisinopril	Prinivil, Zestril	High blood pressure
Metoprolol	Lopressor, Toprol XL	High blood pressure, heart disease
Losartan	Cozaar	High blood pressure
Atorvastatin	Lipitor	High cholesterol
Simvastatin	Zocor	High cholesterol

Table No. 03 Pain & Anti-inflammatory

Generic Name	Brand Name	Used For
Ibuprofen	Advil, Motrin	Pain, inflammation
Naproxen	Aleve, Naprosyn	Pain, inflammation
Acetaminophen	Tylenol	Pain, fever
Tramadol	Ultram	Moderate to severe pain

Table No.04 Diabetes

Generic Name	Brand Name	Used For
Metformin	Glucophage	Type 2 diabetes
Glipizide	Glucotrol	Type 2 diabetes
Sitagliptin	Januvia	Type 2 diabetes
Pioglitazone	Actos	Type 2 diabetes

Table No. 05 Gastrointestinal

Generic Name	Brand Name	Used For
Omeprazole	Prilosec	Acid reflux, GERD
Pantoprazole	Protonix	Acid reflux, GERD
Ranitidine*	Zantac	Acid reflux (recalled in many places)

VII. CONCLUSION

Generic drugs provide a safe, effective and inexpensive option for expensive branded drugs and play an important role in reducing the cost of health care globally. While many countries have adopted policies to promote their use, challenges are in quality assurances, regulatory compliance and priscreber and patient confidence. In India, government efforts such as Jan Ayashi have improved access, but should be done more to ensure a similar quality, especially in rural and low areas. The regulatory structure must be continuously implemented to assure bio -capacity and manufacturing standards. Educating health professionals and public is important to remove misconceptions about common medicines. In addition, encouraging local production and streamlining regulatory approval can increase the market entry and strength. Many blockbuster drugs are ending with patents and healthcare demand is increasing, especially in the aging population, generic is well deployed to play an important role in a permanent healthcare. Price comparison makes it clear that generic drugs can spend 30% to 80% less than their branded counterparts, making them a powerful tool in obtaining accessible healthcare for all.

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