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INDIAN SCENARIO OF GENERIC MEDICINE

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Abstract

This abstract discusses the background and evolution of generic drugs in the United States, focusing on the regulatory framework and the impact of the Hatch-Waxman Act. The research problem addressed is the need to understand the development and approval process of generic drugs, as well as their potential cost savings and implications for public health. The aim of the study is to provide a comprehensive overview of the history, regulations, and benefits of generic drugs. The methodology involves a review of the legislative history, regulations, and approval process for generic drugs, as well as an analysis of the cost savings associated with their use. The context of the study is the United States healthcare system and pharmaceutical industry. The results highlight the significance of the Hatch-Waxman Act in promoting the manufacture of generic drugs and the cost-effectiveness of generic medicines, which are typically 30%–80% cheaper than brand-name equivalents. The implications of the study are that generic drugs offer substantial savings in drug expenditure and contribute to greater accessibility to essential medications.

Keyword

generic drugs, Hatch-Waxman Act, regulatory framework, cost savings, pharmaceutical industry, drug expenditure, public health

Introduction

A medicinal product that is identical to one that was initially covered by a chemical patent is known as a generic drug. After the original medications' patents expire, generic versions of the drugs may be sold. A generic drug has existing approved brand name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics. Generic medicines are typically 30%–80% cheaper than originator equivalents.

Beginning of Generics

"First generics" refers specifically to the first FDA approval that allows a manufacturer to sell a generic medication product in the US. FDA gives importance to reviewing first-generic submissions because it considers they are important for public health.

In 1962, the Kefauver-Harris Drug Amendments were mandated. These changes were introduced in order to mandate that before a medicine could be marketed, drug manufacturers had to provide the FDA with proof of its efficacy and safety. At that time, too, all products that had been put on the market between 1938 and 1962 were considered to be new drugs once more, and establishing products were required to submit efficacy data for analysis based on active ingredient. All related products were taken off the market along with the pioneer product if it was determined that the product was ineffective.

On September 1984, in the 98th United States Congress, the act named The Drug Price Competition and Patent Term Restoration Act was passed, informally known as the Hatch-

Waxman Act, encouraging the government's present system of regulating generic drugs in the United States and the pharmaceutical industry's manufacturing of generic medications.

Pharmaceutical companies were required to submit an abbreviated new drug application (ANDA) to regulatory agencies in order to obtain approval to market a generic drug. ANDA process does not require the manufacturer to carry out repeat testing of generics in animals which is often time-consuming, as their branded versions have already been tested and approved for the safety and effectiveness. the government's current system of regulating generic drugs in the United States and the pharmaceutical industry's manufacturing of generic medications.

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Indian Scenario

These generics will save a lot of money, which can be used for other health issues, especially since India has one of the highest per capita out-of-pocket expenditure rates.

As per the statement made by Minister of State (MOS) for Chemicals and Fertilizers, Bhagwant Khuba, India's pharmaceutical industry stands at the 13th rank in terms of value and volume globally, with over 60,000 generic drugs produced in 60 therapeutic categories." The regulations governing the approval of generic drugs are basically the same globally, with very few exceptions in developing nations. In these regions, bioequivalence (BE) studies are not required in order to obtain approval for generic drugs, and US regulations are the gold standard for regulation in this area.

The 1940 Drugs and Cosmetics Act and the 1945 Rules do not provide a clear definition for generic or branded medications. On the other hand, generic medications are those that have the same active ingredient or ingredients in the same dosage form, delivered via the same route of administration, and with comparable safety and effectiveness to those of branded medications.

The Department of Pharmaceuticals of the Indian government established an innovative initiative called "Jan Aushadhi" (which means "Medicine for People") in 2008. Under this program, government-assisted retail outlets would be set up to serve low-income citizens of the nation with good-quality, unbranded merchandise medications at a fair price. It has assumed the duty of opening Jan Aushadhi stores, which are pharmacies that, to the greatest extent feasible, only sell generic name medications while also giving public sector pharmaceutical

projects a higher priority. 3200 Jan Aushadhi stores were open and operating in over 33 states and union territories in India as of March 15, 2018. Compared to the over 8 lakh retail pharmacies in existence, there are not nearly enough Jan Aushadhi stores—possibly 3200—and manyrural areas remain underserved.

In October 2016, the Medical Council of India amended the program that of conduct for doctors and recommended that all doctors prescribe medications with readable generic names and make sure the prescription is logical and encourages the use of generic medications.

The Indian government may eventually introduce legislation requiring physicians to write generic prescriptions.

Quality Related Issues

"Whether the quality and performance of generic drugs is comparable to the brand drugs" is a question which is frequently posed. Proponents of generic medications maintain that their efficacy is on par with that of brand-name or innovative medications. Following this allegation,

the Drugs Technical Advisory Board of India examined changing Rule 65 (11A) of the Drugs and Cosmetics Act, 1940, in order to allow pharmacists to dispense equivalent brands and/or generic names in lieu of prescriptions for brand-name medications in May 2016. However, detractors have claimed that because generic medications may not have the same bioavailability (BA) as brand-name medications, using them could actually cause treatment failure or even prolong the course of an illness.

The lack of oversight and quality control over generic medication in India is the main cause for concern. We have pleaded with the government that Indian-made generic medications should only be sold through authorized channels and in accordance with all applicable regulations.

Hence, the critical issues that affect the quality of generic drugs are stability , potency ,purity, and drug release, and these should be controlled within an appropriate limit, or distribution to ensure the desired drug quality.

Generic or branded drugs which are manufactured Both are expected to have similar effects. in the country are required to comply with the same standards as prescribed in the Drugs and Cosmetics Act, 1940 and Rules, 1945 for their quality and efficacy. Both are anticipated to have comparable outcomes.

CONCLUSION-

The government should assure quality uniform across all the generics, and specialist in the field of medicine say only then will doctors prescribe them freelly and with confidence.

The absence of rigorous standards for the amount of the drug in its generic variant and the permissible contaminants in it has contributed to doctors' (and patients') lack of trust for generic drugs. Regulators mandate BEs (in vivo) to guarantee therapeutic parity between the pharmaceutical equivalent reference product and the standard reference product. An in vitro dissolution study may be sufficient in some circumstances to demonstrate the equivalency of two pharmaceutical products. An in vitro dissolution exploration may be sufficient in some circumstances to demonstrate the equivalency of two pharmaceutical products. . However, an in vivo–in vitro correlation may not be achievable for highly soluble in water Biopharmaceutics The categorization System (classes 1 and 3), quick-release solutions using currently accessible excipients and manufacturing technology. []But since 2016, clear-cut guidelines have been formulated which state that there should be 90% confidence interval of generic-drug-to-brand-drug ratio for key pharmacokinetic parameters [maximum concentration (Cmax) and area under curve] to lie between 80% and 125% of 1.00. paracetamol, levofloxacin, memantine,

moxifloxacin, Tramadol and temozolomide were given BE waiver by Indian regulator as this drug substances were highly soluble and highly permeable.

The government should also introduce regulations to ensure compliance in the manufacturing and testing of generic drugs in order to ensure that the quality of these drugs is on par with that of their branded counterparts and that this standard is carefully maintained.

The Way Forward

Nowadays, freshman medical students study the concept of generic drugs during their second MBBS teachings in pharmacology. During their subsequent undergraduate and graduate training, the value of generic medications in lowering patient costs is not sufficiently stressed after this initial point. This gap would need to be filled by experts who create medical education programs in order to guarantee that aspiring doctors are knowledgeable about and at ease prescribing generic medications.

Guidelines for BA/BE studies were recently released by the Central Drugs Standard Control Organization, an Indian licensing authority. It has provided a checklist for document submission prior to starting a BA/BE study, but it's unclear if this will ensure the bioequivalence of every single molecule. Our medical community needs to be taught the confidence and practice of writing the prescriptions for generic medications. This can be achieved by educating and informing people about bioequivalence, regulatory issues, and busting myths, doubts, and fears surrounding generic medications. Guidelines on the quality of drugs solely aren't going to be adequate to enhance drug marketing and prescription standards. The FDA's Orange Book offers broad guidance about generic medications and upholds strict rules and regulations to ensure quality. In ultimately, this will boost prescriptions for generic drugs. Every month, the Orange Book lists authorized pharmaceutical products along with assessments of their therapeutic equivalency. In order to support public awareness in order to the area of medicinal product selection, it provides information to prescribers, pharmacists, and state health agencies. Unbranded generic drugs are rarely found in pharmacies or pharmacies other than those operated by the government in hospitals and clinics. When a prescription is written for a generic medication, the pharmacist will probably give out his preferred branded generic. Mandatory prescription of generics is a non-starter unless prescribers have confidence in the generics' quality.

Godman *et al* have proposed a 4”E” (Education, Engineering, Economics, and Enforcement) methodology for promoting generic drug utilization and development in Europe; and the same can be replicated in India. In order to influence generic prescribing, the four "Es" are as follows: (i) "Education": create programs that provide educational materials to physicians; (ii)

"Engineering": concentrate on organizational actions to evolve contracts on the price and volume of current drugs in relation to health management programs; (iii) "Economics": increase the use of generic drugs by providing physicians and patients with positive and negative incentives; (iv) "Enforcement": start governmental or law enforcement methods, such as necessitate generic substitution laws that pharmacists must follow. It is important to plan well-designed survey studies that specifically consider patients as well, community pharmacists, and doctors in order to derive a general picture of attitudes regarding the prescription of generic drugs.

In nations where medical treatment is not prioritized, the cost of healthcare is still rising. Drug prices must be kept reasonable by lawmakers and healthcare providers. One valuable tool for cutting healthcare costs overall is the use of generic medications. Generic versions of pharmaceuticals are predicted to continue to see growth in sales as in greater numbers patents end. A sample list of generic medications that are sold in India, along with their indications, is shown in Table 1

Table

Cost price of a few generic drugs

Sr. No	Drug Code	Name of generic drug	Unit Size	MRP (Rs)	Therapeutic Category
1	511	PARACETAMOL Tablets IP 650 mg	15s	8.03	Analgesic &Antipyretic / muscle relaxant
2	239	Cetrizine (5mg/5ml)Syrup60 ml	60ml bottle	9.60	Antiallergic

3	160	Gemcitabine injection ip200mg vial	vial	182.00	Anticancer
4	142	INSULIN INJECTION 40IU/ml (insulin human recombinant)	10ml vial	71.50	Antidiabetic
5	490	Azithromycin250mg film coated tablet	10s	41.50	Anti infective
6	261	Adenosine6mg/2ml Amp 2ml	2ml	99.50	Cardiovascular system (CVS)
7	313	Alprazolam Tablet IP0.25mg	10s	2.80	Central Nervous System (CNS)
8	115	Calamine Lotion 100ml	100ml bottle	19.52	Dermatology/ Topical/External
9	597	PYRIDOXINE TABLET IP50MG	10S	7.90	Electrolite/Supplement/Vitamin

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With the availability and usage of generic drugs, the experience with these drugs will increase and it will be possible to compare the real-time effectiveness of generic drugs vis-à -vis brand drugs.

Doctors won't be able to persuade patients—including the wealthy—to take generic medications until the real-time efficacy of these medications has been proven and published.If the regulator continues to hold generic drug reviews to strict criteria for quality, safety, and efficacy, our government will be able to accomplish this goal.

Effective collaboration between supporters, health care professionals, and regulators can guarantee that patients receive sound treatment options while also lowering medical costs through the efficient use of generic drugs.

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