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OVERVIEW: GENERIC DRUGS VS. BRANDED DRUGS

[1]Priyanka S. Gawarkar*, [2]Pratibha R. Adnaik, [2]Rahul S. Adnaik

[1]Smt. Kashibai Navale College of Pharmacy, Kondhwa (BK), Pune

[2]Anandi Pharmacy College, Kalambe Tarf Kale, Tal Karveer, Dist Kolhapur

ABSTRACT

A Generic Drug (GD) is a pharmaceutical drug that contains the same chemical substance as a drug that was originally protected by chemical patents. GDs are allowed for sale after the patents on the original drugs expire. Because the active chemical substance is the same, the medical profile of generics is believed to be equivalent in performance. GDs must be equivalent to brand name drugs in terms of active ingredients but it may differ in some characteristics such as the manufacturing process, formulation, excipients, color, taste, and packaging. Branded medicines are medicines, which have a name given to them by a company for advertising. The names of branded medicines are different from the International Nonproprietary Name (INN). Branded medicines may be the original medicine developed by a company or several companies may make the same generic medicine, to which each company gives its own brand name.

Keywords*:* - Generic, Branded, Drugs, Active Pharmaceutical Ingredients (API).

INTRODUCTION

Legislative history

1906 Food and Drug Act (FDA)-Regulates the regulation of food and drugs. Food, Drugs and Cosmetics Act of 1938-creating safety standards. 1962 FDA and C modified Kefauver-Harris repairs-introduction of preventive safety standards and drug efficacy. The Hatch-Waxman Act of 1984 - Compiled briefly with approval of the general copy of all major drugs approved after 1962 [1], meaning that pre-clinical and clinical testing did not have to be prepared for generics.

The intended result of this legislation was to ensure that generic medicines would be less expensive than the equivalent originator medicine because it was not necessary for generic medicine manufacturers to repeat discovery, pre-clinical and clinical studies.

Generic Medicine

GDs are used for identical (or biological) purposes on the original drugs, in doses, strengths, EFF accumulation and safely. To approve GDs, it is necessary to meet the same quality standards as branded products. Even normal production, packaging and test sites must meet the same criteria. Many generic products are manufactured with the same brand name [2]. The term “Generic Drug GDs” or “Generic Medicine” can have varying definitions in different markets; however, the term is commonly understood, as defined by the World Health Organisation (WHO), to mean a pharmaceutical product, which is:

- Usually intended to be interchangeable with an innovator product,
- Manufactured without a license from the innovator company, and
- Marketed after the expiry date of the patent or other exclusive rights [3].

There are differing legal requirements in different jurisdictions that define the specifics of what a generic medicine is. However, one of the main principles underpinning the safe and effective use of generic medicines is the concept of bioequivalence.

Bioequivalence has been defined as follows: two pharmaceutical products are bioequivalent if they are pharmaceutically equivalent and their bioavailabilities (rate and extent of

availability) after administration in the same molar dose are similar to such a degree that their effects, with respect to both efficacy and safety, can be expected to be essentially the same. Pharmaceutical equivalence implies the same amount of the same active substance(s), in the same dosage form, for the same route of administration and meeting the same or comparable standards [4].

The purpose of establishing bioequivalence is to demonstrate equivalence between the generic medicine and the originator medicine in order to allow bridging of the pre-clinical and clinical testing performed on the originator drug.

Prerequisites for GDs**:**

- GDs must meet the same standards as the innovator drug to gain FDA approval.
- GDs, however, do not need to contain the same inactive ingredients as the brand name drug.
- GDs are similar to brand-name drugs in terms of identity, strength, quality, purity, safety, potency, uses and treatment.
- According to US- FDA standards, GDs must have identical active ingredient, dosage form, strength, efficacy, route of administration, drug bioavailability profile and pharmacokinetic (PK) parameters similar to the brand name drug [5].

Brand names and GDs

- Brand name is a drug that a pharmaceutical company has invented, developed and marketed. Once the new drug is discovered, the company creates a patent file to protect itself from copying and selling companies from other companies. Tylenol® is an example of pain reduction. The brand name is Tylenol® and the common name is acetaminophen.
- GDs are similar principles in which brand name drugs have already been approved by the FDA. Generics are only available after the patent mark has ended on the drug name. Patents can last 20 years on certain drugs. The same company that makes the branded drug can also produce a general version or, another company can be formed.

How do different medicines differ from brands?

The main price of the FDF is the price of GDs and brand name drugs. Most producers spend 70% to 90% less than the brand, saving between $ 8 and $ 10 billion a year in pharmaceuticals. Billions are saved by the hospital using more generic. A common drug can also be DFF by brand in terms of size, color or packaging, but the difference lies in the appearance of the drug [6].

Difference between a brand name drug and GDs

The Similarities

According to the FDA for a generic change for a brand:

- It must contain the same Active Pharmaceutical Ingredients (API). (Chemical substance used for drug work).
- The dosage should be the same (number of API, e.g. 20 mg or 40 mg).
- It must be the same dosage form (that is, the original must be available in the same form - for example, liquid, pill, etc.).
- It should have an administrative facility (in the same way that drugs should be introduced into the body).
- It is necessary to bring a large amount of blood into the blood (that is, it must be administered as a brand medicine at the same time in the blood) [7].

The difference:

Here is what generic and branded drugs are different:

- They look different. (Federal law requires it.) - They can have different sizes, sizes, colors or symbols. They have different names.
- They may have different inactive content.-Medications consist of active and inactive components. Some people may be sensitive to passive factors. For example, there are reactions to certain colors used in some drugs.

- The brand costs less than drugs.- Cash prices and co-payment of insurance are generally low. Generators can spend 20 to 80% less, but remember that price is a factor to consider when investigating drugs that are right for you.

- Generators Generic Builders are different, which means that you can get a different version depending on where you buy your medicines and the type of generic.

- Distributed. Various drugs are very generic.-Even the same pharmacy can change general provider [8].

Table No. 1: Regulatory standards required by brand name drugs but not GDs **[12]**

Regulatory standards	**Brand name drugs**	**Generic Drugs** GDs
Scientific studies	Full	Bioequivalence studies
New active moiety	Required	Not Required
New indication	Required	Not Required
New dosage form	Required	Limited
New strength	Required	Not Required
Patent	Required	Not Required
Exclusive marketing	Required	Not Required

Brand V/S Generic - Price Based on the Value of Pharmaceuticals in India:

Generic costs are much lower than those of the brand, and innovation is likely to give the brand competitive price competition. The engineer will be able to reduce or leave a normal version of the innovative new innovator. In general, the general bioavailability and bio-identification (BA/BE) are generally considered well-known brand equivalents. It is thought that the common version will be similar to brand name drugs. The Indian Pharmacological Region is the largest manufacturer and supplier of generic versions in North America, the European Union, the United Kingdom, Japan and Australia. Britain is a highly regulated market with North America, the European Union, Japan and Australia. They are of good quality and are committed to ensuring that citizens of this country get standard medicines; As a result, regulators are active and generally check product quality. Regulators have also decided not only products but also production facilities and human resources. Send their audit

team to ensure that the regulatory agencies have manufactured the product according to the standards set by the regulatory agency [13].

Are Generic Medications as Safe and Effective?

According to the FDA, all drugs, including brand name drugs and GDs, must work well and be safe. GDs use the same active ingredients as their brand-name counterparts and, therefore, have the same risks and benefits.

Many people are concerned about the quality of GDs. To assure quality, safety, and effectiveness, the FDA puts all GDs through a thorough review process including a review of scientific information about the GDs ingredients and performance. Moreover, the FDA requires that a GDs manufacturing plant meets the same high standards as a plant for a brand name drug. To ensure compliance with this rule, the FDA conducts approximately 3,500 on-site inspections each year [14].

About half of all GDs are made by brand name companies. They may make copies of their own medications or another company's brand name drugs and then sell them without the brand name.

CONCLUSION

Generic drugs must be equivalent to brand name drugs in terms of active ingredients. Generic drugs and branded drugs are the answers to better healthcare for all. Generic drugs also tend to cost less than their brand-name. The ANDA process does not, however, require the drug applicant to repeat costly animal and clinical research on ingredients or dosage forms already approved for safety and effectiveness. This allows generic medicines to be brought to market more quickly and at lower cost, allowing for increased access to medications by the public [15].

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