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GENERIC VS. BRANDED DRUGS –A MARKET REVIEW BY QUESTIONNAIRE

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ABSTRACT

A generic medicine is chemically equivalent with a brand name, and generic medicine has lower-cost as compared to band drug, costing is 30-80% less. A branded drug and generic drug has the same active ingredient, dose, safety, strength, usage, quality, and use. In 2008 the average price for branded drugs was $137.90 and the price for generic drugs was $35.22. When new drugs developed by any company they submit it for approval, and the patent is issued for 20-years and they prevent other companies from selling the same drug during the patent period. As patent licenses come near to expiry manufacture can apply to FDA to sell its generic version. Because they did not the same development costs so they can sell it at a discount price. As the once generic version is allowed because of competition they keep the price low. Nowadays, almost 50% of prescriptions are filled with generic medicine. Generic medicines are tested to make sure its performance & its ingredients to meet all the FDA's standards. A survey was conducted in the Science background, Non-science background population, and Pharmacists. For a collection of data, questionnaires were prepared and results were analyzed statistically. The results explain the variable percentage of peoples knows the effectiveness of generic medicines. Only 45% of the science background peoples acknowledge that generic medicines follow FDA guidelines as branded medicines. Thus, if common unity made by physicians and pharmacists it effects on effective medicines may be made at affordable prices.

Keywords*:* - Generic medicines, Branded medicines, chemically equivalent medicines.

INTRODUCTION

The importance of generic medicines is highlighted mainly to reduce the cost of drugs. Drugs are divided into two concepts one is generic vs patented and another is "brand name" vs "non-proprietary" or generic name. The active ingredient in the medicine is the non-proprietary name of that medicine and decided by the expert committee & understood internationally. For example, paracetamol/acetaminophen is a generic name (non-proprietary) and crocin/metal, etc. are brand names. So, most generic drugs are preferred in prescription to patients. Standard medicines are defined as products that are comparable to a brand or listed drug in dosage form, strength, quality and intended to use. Non branded drugs are cheaper as compared to branded drugs which will become a choice for clients. This is because the company does not go through marketing strategies to get this drug popular. The generic name nothing but a copy of branded drug whose patent expires 10 years after it is released to clients. Brand names are usually advertised by industries so more expensive than generic drugs. Industries state that generic drug is not safe and is less effective as compared to banded drugs. In this known fact is that generic drugs are"drugs that are usually intended to be interchangeable with an inventor product which is manufactured without a license from the innovator company and marketed after the expiry date of the patent ".when doctors prescribe generic drugs means they prescribe drugs which are manufactured by other companies after the expiry of the patent of parent drug manufacturer.

Since an abbreviated system (abbreviated new drug application) that designed by the 1984 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) in the US is applicable for approval of generic drugs of all drugs approved after 1962, hence, preclinical studies and clinical trials are not required for generic drugs FDA approval. This would mainly contribute to lower the cost of generic drug production.

Table No 1: Regulatory standards required by brand name drugs but not generic drugs

Regulatory standards	Brand name drugs	Generic drugs
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

Table 1 shows the differences between brand name drugs and generic drugs in terms of regulatory standards requirement. Generic drugs can be launched in the market after the patent expiration date of the brand name drug takes a place. Thus, for generic drug FDA Abbreviated New Drug Application (ANDA) is used, in which many requirements are waived in comparison to new drug applications (NDA).

Similarities between generics and branded medicines

In the market there is a misunderstanding that the concentration of generic drugs can be 80% to 125% of branded formulation means variance may be up to 45% but not true.

1. One important parameter AUC(Area under curve) correlates well with exposure of the drug. AUC means a graph of concentration of blood versus time.

2. The AUC of generic medicines must be not less than 80% or not more than 125% as compared to brand medicines. The range should not clinically significant.

3. Important that a 90% confidence interval of AUC must fall within 80% to 125% and the variance is generally less than 5%.

4. Generic medicines are bioequivalent and will conclude that it produces the same therapeutic effect as the effect of branded medicines so new clinical studies are not required for generic drugs.

In some cases, brand medicines companies produce generic medicines these are called "ultra-generic" or "pseudo-generics.

Difference between generics and branded medicines

1. There may be a difference in inactive ingredients.
2. Products may be slightly different in color, shape or marketing.
3. The important and large difference in cost generics is cheaper than branded.

REVIEW METHODOLOGY

The study was carried out for the following cluster of populations. The cluster was chosen and comprises as follows.

Table No. 2:

SR. NO.	CLUSTER OF POPULATION	NO. OF INTERVIEWED PEOPLES
1	SCIENCE BACKGROUND	50
2	NON-SCIENCE BACKGROUND	50
3	PHARMACISTS	50

QUESTIONNAIRE FOR SCIENCE BACKGROUND POPULATION

1. Did the government of India has passed law & rules for generic medicines?
2. Is there a price difference in Branded & generic Names?
3. Had anyone doctor or pharmacist suggested to use branded to generic medicines?
4. Do you know the reason behind the high price of branded medicines?
5. Do you know generic medicines follow FDA guidelines as that of branded medicines?

QUESTIONNAIRE FOR SCIENCE BACKGROUND POPULATION

1. Do you know what generic medicines are?
2. Are generic medicines are as protective as branded medicines?
3. From where you got information about generic medicines?
4. Generally, your physician prescribes you which type of medicines?

5. Are prescribed medicines available at any medical store?

QUESTIONNAIRE FOR PHARMACIST

1. Are generic medicines available at your medical shop?

2. Are generic medicines easily available to you?

3. Do you advise the patient to buy generic medicines?

4. Do you personally use generic medicines rather than branded medicines?

5. How much percentage of generic medicines containing prescriptions come to your medical shop?

RESULTS AND DISCUSSION

RESULTS OF SCIENCE BACKGROUND POPULATION

1. Did the government of India have passed laws & rules for generic medicines?

Yes- 80% No-20%

2. Is there a price difference in Branded & generic Names?

Yes- 87% No-13%

3. Had anyone doctor or pharmacist suggested to use branded to generic medicines?

Yes- 17% No-83%

4. Do you know the reason behind the high price of branded medicines?

Yes- 67% No-33%

5. Do you know generic medicines follow FDA guidelines as that of branded medicines?

Yes- 43% No-57%

RESULTS OF NON-SCIENCE BACKGROUND POPULATION

1. Do you know what generic medicines are?

Yes- 80% No-20%

2. Are generic medicines are as protective as branded medicines?

Yes- 63% No-37%

3. From where you got information about generic medicines?

Newspaper-47% Hoardings- 20% Television- 10% Pharmacist- 23%

4. Generally, your physician prescribes you which type of medicines?

Costly-73% Cheap-27%

5. Are prescribed medicines available at any medical store?

Yes- 33% No-67%

RESULTS OF PHARMACIST

1. Are generic medicines available at your medical shop?

Yes- 67% No-33%

2. Are generic medicines easily available to you?

Yes- 27% No-73%

3. Do you advise the patient to buy generic medicines?

Yes-30% No-70%

4. Do you personally use generic medicines rather than branded medicines?

Yes-27% No-73%

A) Science background population

I- About 80% of populations said that generics are as effective as branded medicines.

II-Above 86% of populations said that there is much difference in generic and branded medicines.

III- About 67% population said their opinion that brand values responsible for hiking values.

IV- Over 19% said that physicians never discuss differences in prices of branded and generic medicines.

In short, it is concluded that science background peoples well aware of generic and branded medicines and they are interested to switch from branded to generic if the doctor prescribes such drugs.

B) Non-Science background population

I – About 38% of the population did not know about the effect of generic medicines.

II - About 73% propels gives their opinion that prescribed medicines are costly.

III – Over 34% of the population experienced that prescribed medicines of a physician are not available at every medical shop.

IV- over 14% of peoples said that OTC products are equal to generic medicines.

C) Pharmacist population

I) About only 67% of pharmacists stated that they available less stock of generic medicines only because of less demand by patients.

II) About 30% of pharmacists never suggest generic medicines to patients.

SUMMARY

Cost for health care is continuously raising so consumers, suppliers & policymakers think to assist to keep health care needs affordable. Without adversely affecting access. Quality care as a major contributor to prescription drug (branded drug) pricing. The price increase offers an important tool to reduce the rate of growth in generic medicines. Overall health costs. When the maximum patents expire, the generic part of the pharmaceutical market for increased sales will continue. Brand name drugs certainly play an important role in medicine, but generic drugs are a cost-effective alternative. Pharmaceutical costs are on the rise compared to any portion of health care costs. Not only are generic drugs effective, but they are also safe. There are generic drugs Bio-separating their brand name twins. Generics ignore aging, they are usually inferior. More dangerous than new prescriptions. Generic medicines offer great treatment options for patients. But Patients should be told about generic drugs and resolve the myth that "it will be expensive" to Be effective. "That way, if doctors and pharmacists can come to a consensus. The most effective drug can be made available at the best price.

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