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A Review: Generic Drug Prescription

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ABSTRACT:

Generic medicines are the copy of brand medicine having same or deliberate changes in active pharmaceutical ingredient as well as other content. Generic medicines has same mode of action as that of brand medicine for curing respective disease or disorder. As we know brand medicine more costly as compare to their generic competitor. Generic medicines should be studied first for their bio equivalency with brand medicine before they are prescribed. The possible impacts over the Pharmaceutical Sector should be examined.

KEY WORDS: Generic Drugs, Brand name, Prescription, Pharmaceutical Sector

INTRODUCTION:

What is the generic medicine?

Generic medicines were manufactured by the other than the original innovator (patent-holding) after the patent was expired. The term “generic drug” 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,
- is manufactured without a licence from the innovator company, and
- is marketed after the expiry date of the patent or other exclusive rights [1, 2]

A generic medicine is a pharmaceutical product, which is equivalent to a brand-name product in their dosages, route of administration, strength, quality, Kinetics, and its intended use. Generic drug are marketed under its chemical name without advertising. [3-5]

In many other countries, generic drugs are subjected to the government regulations. However, it already introduced in Indian market, but its uses and value still unknown by most of the peoples. As uses and significance of generic medicine is not known to common person, hence its responsibility of the entire aware individual to help and to provide information and awareness about its safety, uses and its effects.

A pseudo-generic product is not a remake but duplicate of the original, made by same company with exactly the same ingredients in the same way. The only difference is the name and packaging. [6-17]

These products are marketed by the same manufacturer at the same price as the original. Pharmaceutical companies make pseudo-generic products to compete true generics and to discourage competitor pharmaceutical companies which from generic product and prevent to entering the market for that particular medicine. [18]

The journey to market—the similarities, the differences

Both brand-name and generic medications undergo similar new drug application (NDA) procedures. The manufacturers of both are required to submit detailed evidence of the chemistry, manufacturing, controls, labelling, and testing processes. From there, brand-name and generic products take divergent paths to market.

New dosage form must undergo different animal and human studies, including large RCTs comparing the efficacy of the new product with that of a placebo and carefully tracking side effects. Bioavailability testing must require. For generic drugs, also known by abbreviated new drug application (ANDA), and bioequivalence studies are sufficient. [19-20]

The bioequivalence studies for new generic was notably by area under the plasma concentration curve (AUC) (Pharmacokinetic) —a measure of overall drug exposure— and the maximal plasma concentration (Cmax). It must be an acceptance range (0.80–1.25 of the brand-name product parameters); the therapeutic equivalence of a generic drug is authenticated. [21, 22]

A. PROLEMS ASSOCIATED WITH GENERIC DRUGS:

Ministries of Health and Family Welfare of Government of India and the states, and Medical Council of India (MCI) have stressed that doctors should prescribe low cost generic medicines and no branded drug should be prescribed. Generic medicine are mandatorily prescribed by the physicians with a view to reducing the cost of healthcare, and the likely law surrounding it, is the culmination of three decades of effort to provide affordable healthcare to the poor. It is presumed that reputed pharmaceutical companies maintain strict quality control of their products as their reputation is a major concern.

1. Regulatory requirement

India's drug regulatory has inherent improvident and insufficient infrastructure. Stringent quality control measures through bioequivalence tests at the USFDA approved laboratory. In the United States (US), the Food and Drug Administration (FDA) is responsible for regulating the drug testing process in order to elicit potential health risks to consumers. [23]

Most of the generic drugs is approved even there is no bio-equivalence data available. Drug Controller General of India (DCGI) take precaution that the patients get the same quality of generic medicine as the branded medicine? For generic drug production there is nothing to lose in case of reputation as like branded medicine manufacturer.

2. Loan licensing and Pharma-Physician Nexus

The any common person like physician and pharmaceutical representative can open a loan licensing company to get higher margins. The bigger competitors ready to pay for keeping their product safe. So that increasing in marketing costs at the expense of patients.

3. Price spikes of Medical Education

The pharma-physician nexus is intensify by the day and along with it are the unjustifiable prescriptions of expensive branded medicine. The rise in cost of medical education, the driving the new beginner into medical practice to recover their education disbursement through unholy contracts with pharma companies.

The price spikes have been the most significant of the issues affecting generics. The majority of pharmacists have seen multiple significant price increases affect the generic drugs they dispense, like Albendazole is a drug that shows the extremity of price shifts, "between late 2010 and 2013, the listed average wholesale price for U.S. patients rose from about $6 to over $119 per typical daily dose" for the drug. [24]

4. Lack of Qualified and Trained Pharmacists in Retail Pharmacies

It is wretched condition there is not a qualified pharmacist on the outlet of retail pharma. To train the pharmacist on the outlet of retail pharma shop floor is very light even the government was taking the precaution. On the other way there was a not included new drug which was recently developed in syllabus of graduate.

5. Absence of Good Governance

That there is clearly a lack of good governance is evident from the fact that the government has been unable to ensure compliance from all the stakeholders despite the presence of well-defined rules governing the manufacturing and selling pharmaceutical products in India such as the Drugs & Cosmetics Act, Voluntary UCPMP (Universal Code of Pharmaceutical Marketing Practices), MCI (Medical Council of India). Yet another law makes no big difference.

6. Evolution or De-evolution?

The modern pharmaceutical industry as we know it today has evolved over many years and contributed significantly to the discovery and development of important drugs. The same industry has to develop future cures too. Therefore, it has to continuously evolve around investments in research and innovation. Let the industry be encouraged to continue in the evolution process.

B. THE EFFECT OF A DYNAMIC MARKET PLACE

It is necessary to understand the distinctions between branded drugs and generics, because the nuance is quite different. A very noticeable difference in prices between brand name and generic drugs exists in several countries around the world.[36] Brand-name drugs have been shown to be priced 20 percent higher than generic drugs in the Netherlands, 30 percent higher in Germany, 50 percent higher in Canada, 50–90 percent higher in the US, and 80 percent higher in the UK. It has been estimated that generic drugs save Canadian consumers nearly $1 billion annually. (26)

In the United States (US), the Food and Drug Administration (FDA) is responsible for regulating the drug testing process in order to elicit potential health risks to consumers. (26) In a perfect world, drug price changes would not affect pharmacy gross profits if payer reimbursement rates moved in tandem with market changes. Unfortunately, the lag in payer response to sudden price increases in the market can cause pharmacies to realize reduced profits or to lose money on prescriptions. While pharmacy acquisition prices increased from approximately $1.50 to $4, NADAC lagged two months behind, and payers were slow to update Maximum Allowable Cost rates, which stood at $1.65 per tablet in late 2014.

EVOLUTION OF GENERIC COSTING TRENDS

When a brand-name drug is in the process of being developed, it often cannot be compared to other drugs containing the same active ingredient, as no similar drugs exist in the market at the time of approval. (27) For this reason, the drug must undergo extensive safety and efficacy testing in the form of preclinical and clinical trials.(28) These trials are associated with considerable financial burden.(29, 30) Brand-name medications are typically 30%–60% more expensive than their generic counterparts.(31,32)

As the use of generic drug medicine as per prescription is increase due to their cheapest cost and easily availability. Hence health authorities worldwide encourage generic medicine prescription and use. In compete with brand drug there is no need for clinical study of generic medicine. However, generic medicines approved by regulatory authorities must bioequivalent to the brand-name medicine; the bioequivalence of generic medicine is compare with pharmacokinetic and pharmaceutical equivalence of brand medicine. (32) Specifically, products are bioequivalent if the pharmacokinetic properties of the comparator compound fall within prescribed limits relative to the reference compound. For example, the US Food and Drug Administration (FDA) and European regulations consider the products to be bioequivalent if the mean maximum concentration achieved, the time at which that concentration is achieved, and the area under the concentration– time curve for the generic product falls within 80%– 125% of the innovator or branded product, when administered under a fed or fasting state. (33, 34)

FUTURE: GENERIC DRUG

Going forward, pharmacies need to respond to the dynamic market situation by doing two things:

1. Drive top-line sales
2. Maintain gross and net margin objectives
3. The person receiving the medicine understands and accepts the substitution;
4. The doctor did not specifically state on the prescription that brand substitution was not to take place; and
5. The specific substitution is permitted in the state or territory in which it was prescribed and dispensed.

To meet these goals, pharmacies should focus on both brand and generic sales. Current trends suggest that many retail pharmacies are increasingly pursuing specialty pharmacy offerings even though payers and manufacturers may want to limit network participation. While generics have traditionally offered a better gross margin, this is now realized on a smaller scale, and at the end of the day, the net profit margin can be similar for both brands and generics. (35)

ADVANTAGES OF GENERIC DRUGS

The generic medicine was often available at low price tan brand medicine, it is often inexpensive option the

consumer and the government who pays for part of the cost of the medicine under the Pharmaceutical Benefits Scheme. Due to low cost generic medicine are easily available as per prescription of doctor

More expensive medicines cant unaffordable by common person, when it was continue repeated. It gives negative health effects: the medication will not treat the intended condition as well as it should – for example, a person's infection may not be completely eliminated if they stop taking antibiotic medicines too early. Having cheaper medication available makes it financially easier to continue with the medication for the whole duration of the prescription.

DISADVANTAGES OF GENERIC MEDICINES

Consumer confusion

Brand-name drugs are, and always will be, the best proven therapy, because of the number and extent of clinical trials they go through. In most cases, however, there is no evidence-based reason to avoid generic substitution for patients who cannot afford the brand-name drug. When in doubt, consult the FDA's. Without properly understanding the similarities and differences between generic and branded medicines, it is easy to become confused and anxious about taking a new medicine. This is particularly the case when someone is used to taking a certain medicine and is introduced to a new medicine that has a different name and appearance but is 'the same'.

There are two main points that you need to understand if you are considering the switch to generic medication:

1. Both the pharmaceutical formulation contain (generic and brand) having same active pharmaceutical ingredient. It may be differ for look and packing only. Don't take two medicines together. This will lead to an overdose of that particular medicine. It must replace or is substituted for another.

2. The generic medicine is alike with the branded medicine. They have same pharmacological effect on body. The only differences exist in the inactive ingredients, which will not have any negative effect unless you have an allergy or intolerance. [(36)]

Not understanding that the new medicine is *substituting* a medicine already being taken can lead to:

- Decrease in medicine adherence due to confusion and anxiety about taking the new medicine; or
- Overdose toxicity due to taking both the branded and generic forms.

If you are not comfortable with the concept of generic substitution, do not switch medicines.

CONCLUSION

1. To change this negative perception of generic drugs, the govt mandatory give instruction to all generic manufacturers their drug must pass in the bio-equivalence testing, comparing it with the reference drug. Due to that the quality of the generic drugs would improve significantly.
2. Ensure that a qualified and trained pharmacist, who has adequate knowledge about drugs and diseases and can improve health awareness among patients, mans all retail pharmacies.
3. Strengthen the Drug Administration Department with adequate manpower to ensure compliance and establish good manufacturing practices (GMP) among all manufacturing units.

Currently, there are an estimated 92,000 pharmaceutical products in India, of which about 60 per cent are different versions of branded-generic or generic versions of single ingredient drugs. It is necessary to impose a cap on the number of generic formulations for each single-ingredient drug. This is by no means exhaustive. It is only to start the process of thinking holistically with a singular purpose of treating the causes and not merely the symptoms.

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