CURRENT REVIEW ON GENERIC VERSUS BRANDED DRUGS

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ABSTRACT

The concept of the generic prescribed drug is widely accepted in various parts of the world. Despite that, it has failed to gain popularity in India due to factors such as nonavailability and distrust of product quality. The cost of medicines is becoming a major regard today. Generic drugs provide a major saving opportunity in healthcare expenditure since they usually have lower prices. Physicians and patients are concerned about their quality although they are bioequivalent of a brand product. We must consult our doctors before deciding if a generic is right for us. This brochure gives you the information you need to help you decide what’s right for you in your treatment and recovery. Our paper is focused on the comparison between the brand and generic drugs and also shows the generic drugs are beneficial to human use and what are the pros and cons of generic and branded drugs.

Keywords: - Generic–branded, cost of medicines and regulatory standards.
INTRODUCTION

Generic drugs

A generic drug is a pharmaceutical drug that contains the same chemical substance as a drug that was originally protected by chemical patents. Their pharmacological effects are the same as those of their brand name. [1-4]

Pros and cons of generic drugs –

Pros-

• Low manufacturing cost.
• Low marketing investment
• Low retailer margin.

Cons-

• Risk of sensitivity or intolerance due to different inactive ingredients.
• Not all medicines can have generic alternatives.

Brand drugs

A drug that has a trading name and is protected by a patent. This drug is medicine discovered, developed and marketed by a pharmaceutical company. [4]

Pros and cons of brand drug –

Pros-

• They are safer.
• Brand names are easier to read and remind for pharmacist and patient.

Cons –

• High manufacturing cost
• High marketing

• High retailer margin

India is the fourth-largest producer and tenth largest exporter of drugs in the world. Major Indian population does not have access to even essential medicines [1]. Due to the poor accessibility and affordability of people in India, generic must be made available to minimize the cost of treatment. With high healthcare costs, interest in generic drugs has increased all over the world. The increased production of generic drugs from 49% of the global drug market in 2000 to 78% in 2010.[7] Generic drugs in simple terms are the copy of the branded ones having the same ingredients, same dosage, same indications and exactly same pharmacological effects as the manufacturing companies use the same active ingredient in both types of formulations [8].

A generic drug is the same as a brand name drug in dosage, safety, quality as for approval of any drug bioequivalence (BE) data that match the BE data of brand name drug is necessary. In BE studies using the same route of administration pharmacokinetic parameters and drug bioavailability of both medication are given in the same amount of drug given to the same number of healthy volunteers under specified conditions [9]. Several studies have demonstrated that has no difference in replacing brand name drugs with generic drugs. In contrast, adverse drug reaction was recorded during the trial of the study on replacing a brand name drug of extended carbamazepine release formulation with the equivalent drug. BE does not always correspond to therapeutic equivalence.

**Difference between generic and branded drugs –**

• Both look different, different shapes, sizes, colors.

• Might have different Inactive ingredients (even active ingredients do not differ between brand name drug and generic drug, other excipients may be different, this can cause a problem in patients sensitive to excipients).

• Generic costs are less than the brand name drug.

• Generics vary by manufacturer, which means you could receive different versions of based on where you purchase your medications and what type of generic they dispense.[3]
Table No. 1: Regulatory standards required by brand name drugs but not generic drugs [5]

<table>
<thead>
<tr>
<th>Regulatory standards</th>
<th>Brand name drugs</th>
<th>Generic drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific studies</td>
<td>Full</td>
<td>Bioequivalence studies</td>
</tr>
<tr>
<td>New active moiety</td>
<td>Required</td>
<td>Not Required</td>
</tr>
<tr>
<td>New indication</td>
<td>Required</td>
<td>Not Required</td>
</tr>
<tr>
<td>New dosage form</td>
<td>Required</td>
<td>Limited</td>
</tr>
<tr>
<td>New strength</td>
<td>Required</td>
<td>Not Required</td>
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<tr>
<td>Patent</td>
<td>Required</td>
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<tr>
<td>Exclusive marketing</td>
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SUMMARY

The original concept of generic distinguishes these products from the patented or innovator products marketed by a company that has invested a lot of time money and effort into research. The economic benefits of generic drug use are well known and undisputed. Due to the limited availability of quality generic formulations, widespread generic prescribing and dispensing activity are difficult. In this study, we observed that the generic drugs are the same effect as brand drugs and their cost is less also. The cost-benefit does not remain restricted to the retailers it is also available to the patients in appropriate proportion.

CONCLUSION

The generic drugs have the same active ingredient as brand drugs, the idea that higher prices mean higher quality is not true for pharmaceuticals. For most plan members generic medications provide the best overall value. Generic drugs are less costly and are affordable for all populations.

REFERENCES


8. FDA Fact sheet what’s involved in reviewing and approving generic drugs application?