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Importance of Generic Drugs: A Review

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Review Article

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ABSTRACT

A drug is a chemical substance which is used to treat or diagnose a disease. Its takes many years to discover a new drug as it has to undergo many tests, clinical trials etc., in order to pass the USFDA standards. Only if the drug is approved in the USFDA it is permitted to get manufactured in the pharma industries. Once the drug passes the stag of USFDA s' approval it is then manufactured and the discoverer of the drug gets the patent for that drug. As the drug research is too costly based on the expenditure of the research, the discoverer decides the price for the drug which is too high, at least not affordable by common man. For this reason the introduction to generic drugs has introduced.

INTRODUCTION

A generic drug is a pharmaceutical drug which is equivalent to a brand-name product in dosage, route of administration, strength, quality, Kinetics, and its intended use. It may also refer to any drug which is marketed under its chemical name without advertising [1-12]. For getting the approval to market the generic drug an abbreviated new drug application termed as ANDA is to be submitted by the drug companies. The Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, allowed ANDAs to be possible by making a compromise in the drug industries [13-28]. Hence, the generic drug gained access to the market for the prescribed drugs and discoverer companies gained restoration of patent of their products. Any new drug is developed under patent protection. This patent protects the investments involved in the development of the drug by allowing the company to have the right to sell the drug while the patent is in the effect. The manufacturer can apply to the FDA for the selling of generic version after the expiration of the patent period. Further, the ANDA process doesn't require the sponsor to repeat test animals, ingredients or dosage forms which are already approved for the safety and its effectiveness.

In many countries generic drugs are subjected to the government regulations. However, it has been already introduced in our country yet its uses and value is still not known by many people. The significance of these drugs is not known by the common man, it is the responsibility of all the aware individuals to help people understand and spread its awareness about its safety and its effects.

ARE GENERIC DRUGS AS GOOD AS BRAND-NAMES

As similar to the brand drugs these generic drugs also need to get approval from FDA mentioning the composition, administration dosage, drug kinetics is same as to the brand named drugs [1,7,9]. The FDA needs the generic drugs to be high in quality, and same as pure, strong and stable as brand name drugs. The have same active ingredients, same risks, and same benefits as the brand-name drugs. Following the regulatory agencies and manufacturing techniques the tests are performed. To get approval, the criteria of dissolution rate of both the brand and generic drug should be same along with same safety, dosage and efficacy [29-47].

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WHY DO GENERIC DRUGS LOOK DIFFERENT THAN THE BRAND-NAME PRODUCT?

As per the US based trading laws the generic drugs must not resemble as same as to that of the original brand drugs, so only the colour and shape varies. Maintaining its effectiveness, colours, flavours, and few certain other inactive ingredients can be different [48-63].

JAN AUSHADHI YOJANAM

Over the last few years even our country has developed in producing quality generic drugs in most of the thereupatic categories. However, these generic drugs are available at reasonable prices but still most of the population of our country is still unable to afford these drugs [64-90]. In our country, generic drugs are developed in most of the therapeutic categories. Even though, these generic drugs are made available at reasonable prices, most of the population is still unable to access the generic drug usage. So, in order to make it available to layman, the government has introduced the Jan Aushadhi Scheme, making the availability of generic drugs and helping to get medicines at affordable prices. This Jan Aushadhi stores are presents all over the country enabling the availability of drugs at reasonable prices having 600 plus drugs. The Jan Aushadhi stores are licensed under the roof of pharmaceutical products of India [91-100] Table 1.

Table 1. Jan Aushadhi Yojanam scores.

			JAN AUSHADHI PRICE		BRAND PRICE	
S.NO.	NAME OF MEDICINE	Unit	(Including All Taxes)	Brand	Including all Taxes	Differnce In Price
1	Aceclofenac+Paracetamol (100 mg+500 mg) Tablet	10's	14.49	Zerodol-P (Ipca)	38.5	24.01
2	Acetaminophen+Tramadol Hydrochloride (325 mg+375 mg) film coated Tablet	10's	8.16	Ultacet (Johnson & Johnson)	142	133.84
3	Amikacin 100 mg inj.	Vial	15.04	Amiject (Alkem)	27	11.96
4	Cefixime (50 mg/5 ml) Dry syrup	30ml	25.93	Taxim-O (Alkem)	42.21	16.28
5	Glimepiride 1 mg Tab	10's	3.48	Glimestar-1 (Mankind)	22	18.52
6	Insulin Injection IP 40 IU/ml (Insulin Human Recombinant)	10 ml	118.61	Huminsulin (Eli Lilly & Company)	141.24	22.63

CONCLUSION

So, in a country like India which is still under that stage of developing we need to bring awareness and help the people know the value and use of these generic drugs. As the drugs are with same composition and provide the same therapeutic effect at reasonable prices these should be promoted to a larger extent.

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