Analysis of generic and branded drugs

A Branded drug company invests a lot of money on the research and development of a new drug. After the discovery of a lead compound and before conducting the clinical trials, the company can apply for a patent. Once the patent is obtained, the company gets exclusive rights to manufacture the drug and to exclude other companies from manufacturing the drug. The branded drug company enjoys the monopoly of manufacturing and marketing the drug until the patent expires. The cost of a branded drug is very high as the company tries to recover the money invested in the research, development and marketing of the drug. Once the patent has expired., generic drugs enter in to the market. Are these generic drugs as safe and effective as the branded drugs? Yes they are. Then why are they so much cheaper than the branded drug? Because, unlike the branded drug company, generic drug companies need not invest a lot of money on research and development and their overall investment in bringing the drug in to market is very less compared to the branded drug. As generic drugs are as safe and effective as the branded drug and relatively cheaper than the branded drug, patients prefer them. This leads to a fall in the branded drug market which ultimately leads to a fall in its price because, market conditions such as, number of sellers, barriers to entry etc. determine the level of competition in a market. Some companies try to avoid this by various methods. One of such methods is “ Evergreening of patent”.

INTRODUCTION:

There is a long standing debate on whether generic drugs are as effective and safe as the branded drug. A brand name drug is a medicine that is discovered, developed, and marketed by a pharmaceutical company and is

protected by a patent. A generic drug is said to be a bioequivalent of the branded drug and does not have a patent by it self and is manufactured and marketed only after the expiration of the branded drugs patent. Brand name drugs are well known and trusted but are expensive. Generic drugs are less expensive than the brand name drugs but drugs are not always trusted by the people. How ever, the final decision to choose a brand name drug or a generic drug involves both the patient and the health care team.

According to Howland(2010), “ The concept of bioequivalence is used by the U. S. Food and Drug Administration, (FDA) to evaluate and approve generic drugs without additional safety and efficacy studies”. As per FDA, generic drugs should have the same active ingredient, dosage strength, route of administration and should be the same dosage form as that of the brand name drug even though they have different inactive ingredients and look different from the branded one. All generic drugs are tested for safety, efficacy and bioequivalence with the brand name drug before they are approved by the FDA and marketed. But the branded drug is of higher cost than generic drugs. Most people do not realize that, when they buy a branded medication, they are not just buying that drug but they are also paying for what it took to develop that drug and wonder, “ why branded drugs are so expensive than the generic drugs?” The higher cost of the branded drug is due to the large investment in research and development by the company and generic drugs does not need this investment and hence they are so cheaper.

Branded and Generic drugs :

It takes about 10-15 years to discover a drug, develop it and make it available in the market for treating the patients. The average cost of this entire process is estimated to be $800 million to $1 billion. This includes the cost of thousands of failures. For every 5, 000 to 10, 000 compounds, that enter the research and development, only one receives approval. Once the drug is approved by the FDA, the pharmaceutical company can apply for a patent. A patent provides the company, the right to exclude others from making, using, selling, or importing the patented invention. In the US, patent provides a protection of 20 years, but it is applied from before the beginning of clinical trials. So the effective life of a drug patent could be between 7-12 years. Once a patent is obtained, the pharmaceutical company enjoys a period of market exclusivity or monopoly, during which the company is able to set the price of the drug so as to maximize profitability. This high price can help the drug company to make a significant profit on their investment in research and development. Generic drugs cannot be produced legally until the patent has expired or the generic company certifies that the brand companies patent is invalid or in countries where the patent is not in force. Once the patent of the branded drug has expired, any pharmaceutical company can manufacture and sell that drug and hence generic drugs come in to play, which prevent the branded drug company from dictating the overall market price of the drug. A generic drug must contain the same active ingredient as the original formulation. With the entry of generic drugs into the market, there will be a significant fall in the price of the branded drug which is due to the lower price of generic drugs. Generic drugs save the patients and the insurance companies substantial costs.

Are generic drugs as safe and effective as branded drugs?

According to the U. S. Food and Drug Administration (FDA), “ generic drugs are identical or with in an acceptable bioequivalent range to the branded drug with respect to pharmacokinetic and pharmacodynamic properties.” Two drugs are said to be bioequivalent, if their rate and extent of availability after administration are similar to the extent that their safety and efficacy can be expected to be same. This implies that the generic drugs are identical by dose, strength, route of administration, safety, efficacy, intended use and they have the same active ingredient. Law requires the generic drug manufacturers to prove the bioequivalence of their drug with the branded drug and the range of bioequivalence should be between 80%-125% of that of the branded drug. Bioequivalence does not necessarily mean that the generic drug should be pharmaceutically equivalent to the branded drug and some chemical differences may exist. According to the Hatch-Waxman Act, an applicant should file an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration and demonstrate the bioequivalence of his generic drug with the branded drug in order to get an approval. FDA , approves the drug, if it feels that the generic drug is bioequivalent with the innovator drug. Hence all the marketed generic drugs are bioequivalent with the branded drug and are therefore safe and effective as the branded drug. But in some cases, generic drugs may show some undesirable effects which are not seen with the branded drug. For example, in 2007, patients who switched from an anti-depressant branded drug, Wellbutrin XL 300mg to its generic version Budeprion XL 300mg experienced certain undesirable effects.

Why are generic drugs so cheaper than the branded drugs?

The generic drugs are very cheaper than the branded drugs. The main reason for such low price of generic medicines may be the competition among the drug manufacturers when drugs are no longer protected by patents. Generic drug manufacturers need not invest a lot of money in drug discovery and development. They also need not prove the safety and efficacy of the drug through clinical trials as they have been already conducted by the branded drug companies. Hence companies incur fewer costs in producing the generic drugs. Media advertising and other marketing efforts by the branded drug companies also help the generic drug companies in reducing their investment in marketing. Many generic drugs have already been in the market for decades and are well-known to the patients, but often under their branded names. Hence all the above facts make the generic drugs much cheaper than the branded drugs.

The process of ever greening the patent:

Large pharmaceutical companies often spend some millions of dollars to protect their patent from generic competition. When the patent is about to expire, some patent holders try to extend the patent by various methods. They include: taking new patents, buying the competitors, frustrating the competitors etc. It is not a formal concept of patent law, but is referred as a social idea that is utilized by the pharmaceutical patent owners to extend their privilege of monopoly over the highly profitable branded drug, thereby preventing the entry of generic drugs in to the market. Some times the branded companies may use some other methods like licensing a subsidiary to sell generics under the original patent.

Exclusivity to generic drugs:

In specific cases, a patent exclusivity of 180 days is offered by the FDA to the generic drug manufacturers in specific cases. During this period, only one generic drug manufacturer can manufacture the generic drug. This exclusivity period is offered only in cases when a generic manufacturer argues that a patent is invalid or is not violated in the manufacture of a generic drug. For example, Simvastatin was manufactured and marketed under the brand name Zocor by Merck & Co. When this company lost its patent in 2006, Ranbaxy laboratories and Teva Pharmaceutical Industries obtained a 180 day patent exclusivity period for Simvastatin.

CONCLUSION :

Finally it can be said that, generic drugs are of at most importance because, studies say that, generic drug substitution of prescription drugs could save $88 billion of money spent on medical care in United States. Even though there are certain exceptional cases, it can be said that generic drugs are as safe and effective as the branded drug, because generic drugs are marketed only if they are approved by the FDA to be bioequivalent to the branded drug and they are cheaper because generic drug companies need not invest a lot of money on research, development and advertising of the drug. This makes the generic drugs more preferable and acceptable by the patients and today more than 70% of the drugs marketed are generic drugs.

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