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GUEST EDITORIAL

Generic versus branded medicines

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Generic medicines are produced by manufacturers other than the original innovator company that holds the patent for a particular pharmaceutical product. Such products can be marketed after the expiry date of the patent or other exclusive rights enjoyed by the original innovator company. A generic medicine contains the same active ingredient as the original product manufactured under patent, with the same dose, route of administration and concentration. It is essential that the generic medicine has the same bioequivalence, quality, performance and intended use for the same disease condition, as the innovator product. The name of the medicine, its appearance and packaging can be different from the original research product with the brand name. Ideally the generic medicine should be marketed with the name of the active ingredient contained in it. As the expenses incurred by the original innovator company for research and development, clinical trials and marketing are generally very high, the company sets a high price tag for the drug during the period of patent rights. Once this period of exclusive right is over, the same drug can be manufactured and marketed by other companies at a much lower price with a generic name.

Why Generic products are necessary

The use of generic products are necessary to reduce cost of treatment and to increase access to healthcare service, particularly in a developing country where the healthcare delivery system is not robust enough, unlike developed countries where the healthcare budget enjoys a significant percentage of the GDP. In order to achieve these objectives, a system of rigorous quality control and safety measures for the pharmaceutical products are essential. In a developing country like ours, the generic products available in the market may greatly vary in quality, because of the lack of clear and specific requirements for generic pharmaceutical products. It has been agreed by various authorities that the bioequivalence and bioavailability of the active ingredient of the generic medicine must be identical or 'interchangeable' with the original innovator product. Only then the generic product will be appropriate clinically as a substitute. The WHO speculated that up to 30 % of the total drug market in some developing countries where the regulatory system is not very active may be counterfeit.[1]

The cost factor

The cost of medicine and other pharmaceutical products, surgical appliances and implant devices as a percentage of total health care expenditure has been rising worldwide, so also in India due to high cost of innovator products. Prescription of generic medicine has been an accepted practice in many western countries including USA and UK, and the proportion of generic prescription in comparison to branded products is gradually rising to reduce the cost of treatment. In some countries it is a part of training for the medical students to learn about generic drug prescription. In our country the procurement price and the retail price of many generic drugs manufactured by reputed pharmaceutical companies vary widely with a high profit margin for the retailers. This adversely affects the users by raising the cost of treatment unnecessarily.

Multiplicity of products

In the Indian pharmaceutical market, there are large numbers of brands for the same pharmaceutical product available in the market to choose from, which causes further confusion in the minds of the users. Mathew, in a study from South India has divided the various types of pharmaceutical products into innovator brands, most-selling generics, least-priced generics and unbranded generics, with the innovator brand being the most expensive and the unbranded generics the least expensive.[2] Most selling generics, also referred to as branded generics by some, are widely available products in the market under various names. The manufacturing and marketing companies try to keep their own identity visible, and compete with each other for increasing their market share. In the process, they offer higher profit to retailers, while spending large amount for promotional activities. Not only the purchasing public but also the physicians and pharmacists get confused whether these are branded medicines or generics.

The unbranded generics

The unbranded generics which are supposed to be the least expensive should be marketed and prescribed by the name of the active ingredients in them. Very often the physicians while prescribing find it difficult to remember the pharmacological name of the active ingredient. The retailer

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pharmacists find it more difficult to dispense it as they are confused by the large number of branded generics available in his pharmacy. In the process the pharmacists tend to dispense the product which is sold with the highest profit margin irrespective of the quality. Most of the private pharmacies of our country are not manned by qualified pharmacists, and the persons dispensing the medicines have no knowledge and training regarding prescription of generic medicines. As a result of this they are guided by the representatives of the manufacturing companies and marketing agents. Although there may be difference in the efficacy of various branded generics available in the market, physicians tend to prescribe drugs marketed by reputed pharmaceutical companies, without noticing that the drug may have been manufactured by lesser known manufacturers.[2]

In case of unbranded generics, unattractive packaging and lack of promotional activities leads to less popularity of the products. The physicians also feel it cumbersome to write fixed dose combination drugs with the generic names. Particularly, in a busy government hospital where the out-patient clinics are always over-crowded, it will take lot of extra time for the prescribing physicians to write fixed dose combination drugs by generic names. Added to this, in Indian Medical Council Professional Conduct, Etiquette and Ethics Regulations 2002, it is clearly mentioned that "Every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs".[3]

Studies from India

There have been many published works from various countries of the world dealing with the efficacy, popularity, prescribing habits of physicians and benefits of dispensing generic drugs. There are also some such studies published from India analyzing the various aspects of use of generic medicine. Das et al, in a study conducted in West Bengal found that generic drugs sold by fair price medicine shop established in the government run hospitals under Public Private Partnership (PPP) mode, have better acceptability to the patients.[4] Singal et al in their study observed that the government must take up generic promotional activities, create awareness on use of generic medicine to build confidence among physicians, pharmacists and the users, make the generic medicine freely available in the market with lower price tag and assured quality.[5]

Government initiative:

More use of generic medicine is going to ease the ultimate healthcare expenditure of the government. Government initiatives are to be directed towards educating the healthcare professionals to create more awareness about generic drugs. Some knowledge about generic medicine and method of writing generic prescription should be taught during the undergraduate medical course. Similarly students of pharmacy course should also have some knowledge about generic medicine. Some attention is also required for the large number of untrained dispensers working in the pharmacies throughout the country. At the same time strict quality control and market regulations are necessary. All states must have adequate set up for modern and well equipped drug testing laboratories to standardize the efficacy of the generic drugs available in the market. There has to be some mechanism to reduce the wide difference between procurement price and retailer's price, so that the public gets the benefit. To avoid confusion, something has to be done to restrict the innumerable branded generics available in the market. Preparation of an all inclusive essential drug list (EDL) for all government health establishments and making these drugs available in their true generic form with the minimum price tag will help in reducing health care expenditure. Meanwhile, non-essential details like doctors writing prescriptions in capital letters may take a back seat for the time being.

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