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Generic Medicines: Old wine in new bottle?

Trupti Rekha Swain and Prajna Paramita Giri[1]

Department of Pharmacology, In Charge Clinical Pharmacology Unit, SCB Medical College, Cuttack, Odisha, India.

[1]Tutor, Department of Preventive and Social Medicine, SCB Medical College, Cuttack, Odisha, India.

ABSTRACT

Generic medicines are cheap but effective alternative for improving access to life saving medicines in a country like India. Increasing challenge is being faced by the Indian generic industry because of gradual stricter regulatory requirements. In the process, generic medicines add cost. Increasing costs for maintaining quality assurance, anti-counterfeit steps are also challenges the generic industry is facing now. Some originator companies tactfully mislead the physician and public that generic medicines may be less safe and effective than their branded counterpart. Mass sensitisation regarding the generics, educational efforts and better communication among patients and health care professionals, are seen as major drivers to enhance confidence on generic medicines among consumers.

Key words: Drugs, Generic, Industry, Originator.

INTRODUCTION

The provision of an effective healthcare system in any country is a complex equation balancing appropriate levels of patient care with resources availability. Generic Medicines are one of the most cost effective tools in modern health care having remarkable health benefit. These medicines play an essential role in treating disease by increasing the accessibility and affordability. The growing cost of healthcare is unavoidable in today's climate; drug expenditure is forecasted to increase by around 5% annually over the next 3-5 years. A long-term approach involving increased utilization of generic medicines could compensate for some of this rising expenditure without compromising outcomes.

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A generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights.[1] Generic medicines contain same active ingredient as original/innovator molecule, identical in dose, strength, route of administration, safety, efficacy and intended clinical use. Thus these drugs are only bioequivalent version of original drug that can only vary in shape, size, color and taste.

The drug market situation is a little different in India than the USA or other developed nations. In the USA, when a new drug is launched only the company that holds the FDA patent are legally allowed to sell the drug, thus giving them market monopoly. In India however there was different patent law (Process patent) till 2005 which meant that anyone could replicate any drug in India without legal ramifications. This led to the trend of branded generic drugs which has 99.5% of the country's generic drug share. Sometimes, any organization, or state Govt. can

Address for correspondence:

Prof. Trupti Rekha Swain, Associate Professor, Department of Pharmacology, In Charge Clinical Pharmacology Unit, SCB Medical College, Cuttack, Odisha, India. E-mail : drtruptiswain@gmail.com

prepare generics in their own manufacturing unit providing authenticity to the medicines. These drugs are designated by some as "pure generic drugs" in our country.

Advantage of Generic Medicines

Expiry of patency allows different pharmaceutical companies to compete for same drug production. Because generics are only bioequivalent version of original medicines; they do not incur the cost of drug discovery. Generic manufactures, do not bear the burden of proving safety and efficacy of the drug by clinical trials. In addition the generic manufactures receive the unseen benefit of previous marketing efforts of the originator drug company, including media advertising, drug representatives and distribution of free samples.

Challenges to the Generic Medicines industry

Increasingly Stringent Regulations

The generic medicines industry in today's environment faces an increasing regulatory burden such as Pharmacovigilance requirements; periodic safety updates (PSURs) and the introduction of specific packaging. Rising costs in quality assurance, anti-counterfeit measures and product security are also a major challenge and must all be absorbed without the ability to counter them with price adjustments.

Costs and Pricing

In most instances, manufacturing cost levels for generic medicines are the same as those for an originator product. Often, the only flexible parameter for reducing costs lies within the price of the active pharmaceutical ingredient (API) which may fall over time as API manufacturers face their own competition. All other costs tend to be fixed; with little room for manoeuvrability. This is the reason why any downward pricing adjustment by an originator company prior to generic entry creates problems for the generic medicines manufacturer.

Generics in Consumers Perspective

Some originator companies continue to imply that generic medicines may be less safe and effective than the branded counterpart. This is considered to be an unfounded claim. Indeed, a recent review and Meta analysis, looking at the clinical equivalence of generic and brand-name drugs used in cardiovascular disease showed no superiority of the originator medicine over the generic medicine.[2] In the absence of sound clinical data, a 'fear factor' among the public by the originator company is a common phenomenon. Patient confidence and knowledge pertaining to generic medicines have not changed over the past few years, especially in our country. Mass educational efforts and greater communication among patients and health care professionals, were seen as major drivers to the uptake of generic medicines among consumers.

Legal Issue in India

Indian generic market has made its presence felt from Africa's crowded AIDS clinics to the malarial dispensaries of Southeast Asia. India is among the world's top five drug producers in terms of volume; though its $7 billion market does not rank as high in value.[3] Some Indian pharmaceuticals have even made headway in the USA market. Patent law in India was amendments in the year 2005 because of dire necessity to comply with its WTO obligations on intellectual property. In today's world, when medicines are considered as fundamental human right and there is lot of skepticism about patent systems, it remains to be seen whether the modified Indian patent system withstands the true test of time.

CONCLUSION

Indian generic industry time and again has proved its superiority in world market. Health care providers should exploit the situation for improving acceptability of essential life saving medicines in our country.

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