Only for Pharma people

Volume 2, Issue 9 September 2019, 30/-

QualPharma

The Learning and development Journal

METHYLCOBALAMIN

An indispensable micronutrient

GENERICS MODEL IS INDIA READY?

294 Drugs banned since 2007 [FATE NOT YET DECIDED]

VG Somani appointed new Drug Controller General

Deputy Drug Controller Naresh Sharma arrested

Warning letter issued to Lantech Pharmaceuticals Limited

USFDA Approval

Digital transformation of the Pharma companies in India

Part 2 Attitudinal shift to rethink, reimagine & repurpose business model

Phytate and Phytase

Medicinal values of plants

Drug and Cosmetic Act [Series –3]

How to address 483s on Sec. 211.192 Production record review

ZODIAC PREDICTION

Mr Dilip Shanghvi

The Tycoon of Pharma Industry

GENERICS MODEL- IS INDIA READY?

Dr Sanjay Agrawal

Dr Agrawal founded PHARMA CONSULTANTS and INVENTOR to fulfill his passion, capabilities and desire to assist pharmaceutical companies around the globe. He has actively worked in pharmaceutical and related industries for more than 28 years and started this firm in 2005. He is **Editor-in-Chief** of renowned IJM Today and honorable member of the editorial board of **The Antiseptic**.

Introduction

Branded versus generic drug is a topic of debate and discussions among physicians, drug regulators, and policy makers across the world. Several pharmaceutical trading agencies such as wholesalers, retailers, and drug manufacturers describe that **branded drugs** are superior to **unbranded drugs** through advertising and promotion. Drug manufacturing companies in India market same molecule under many brand names at various prices. **But according to the medical experts, they trust drugs which are made by reputed pharma companies.**

The drugs are available in three names:

- Branded
- Branded generics and
- Common name i.e (generic name)

Branded drug

A branded drug is protected by a patent and has a trade name. The drug cannot be manufactured or sold by any other company. The rate is fixed by them. New drugs are generally developed under patent protection for 20 years from the date of submission of the patent. This provides protection for the innovator of such drugs to make the initial costs incurred by the company, viz., R&D and marketing expenses to develop the new drug.

The brand name in true sense, is the name given by the innovator company who is holding a patent for that product. **On expiry of patent, the drug molecule is free to be manufactured by other companies and sell them in generic name.**

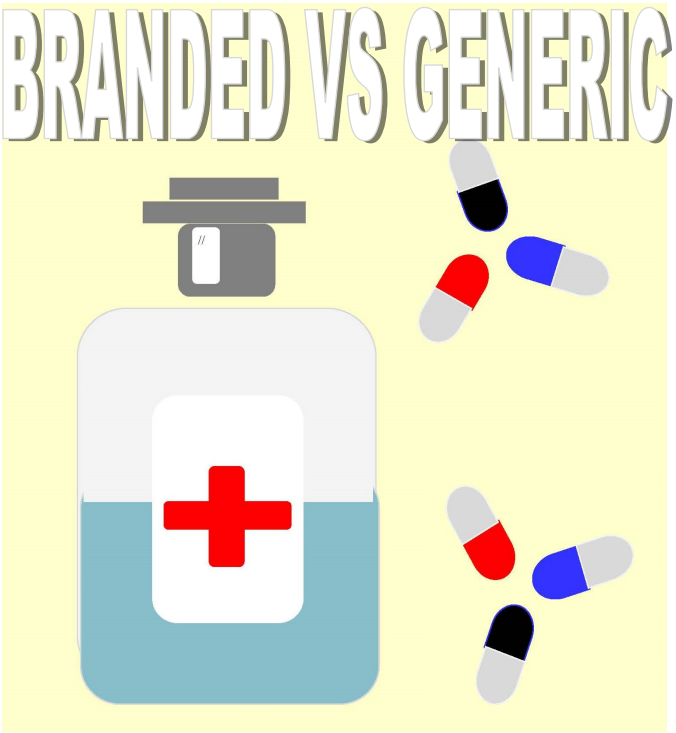
The branded drugs are priced at higher level because the pharmaceutical companies spend huge amount to build the brand value. When a pharmaceutical company is given sole rights of manufacture and market, the drug is said to have a patent on it. For a period of time after the patent is granted, no one else can produce a drug that is the same as the patented drug; the medicine belongs exclusively to the original company. For this reason, branded drugs are the most well known and most trusted type of that particular drug.

There is a new term called **Branded Generics** which is unique to India. where the off-patented drugs sold in brand names called branded generic drugs.

As far as pharmaceutical market is concerned, there is no difference between brands and branded generic drugs. Both groups are sold in brands only.

Generic drugs

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. Generic drugs are marketed under a non-proprietary or approved name rather than a proprietary or brand name. It must be frequently as effective, but much cheaper than brand-name drugs. Generic drug manufacturing companies do not have to spend expenses on R&D to find out for a new chemical entity (NCE) and that is why these drugs are less in cost compared to branded medicines. Because of their low price, generic drugs are often the only medicines that the poorest can access.



The common name or generic name is the name of the drug molecule for which no ownership exists. This name for a molecule is given as international non-proprietary name by the WHO

According to a recent study, India's trade margin for many branded drugs varies from 200 per cent to more than 2000 per cent. In developed nations such as the US, UK only patented drugs are sold under a brand, which is marketed through their understanding by the medical doctors. Off-patent drugs are sold only as pure generic and without using any brand name.

It helps in making pure generic drugs with low cost. But, in India, the most of the generic drugs are sold as their **brand generic drugs.** Margins on sales of brand name drug is much higher for everyone in the supply chain.

Despite stringent price control, the big pharmaceutical companies manage to spend exorbitantly on branding of their drugs. Since advertisement of prescription medicines are not allowed in the country, companies or medical representatives push their products through medical doctors, chemists and distributors in lieu of freebies.

INDIAN SCENARIO

In India, quality of generic drugs is not considered at par as brand name drugs. For obtaining quality standard of brand drugs, generic drug manufacturers will have to invest in equipments and necessary approval process which may increase the cost of generic drugs.

Also, in developed countries, the community pharmacists play an important role in dispensing medicines and hence their cost awareness becomes crucial. But in India, the concept of community pharmacists doesn't exist and hence the onus for cost reduction, from the point of view of drug selection, lies with the doctors and doctors have poor knowledge of cost of different brands.

In developing generic drugs, the manufacturer must prove the bioequivalence of the drug with that of branded drug. The purity, consistency and strength have to be maintained. In this process there is no involvement of lengthy and other expensive clinical trial process except the bioequivalence tests. Thus generics can take only about maximum of three years as compared to the branded drugs which takes about six to seven years for the development.

The generic prescribing is proved to have many positive points. It avoids the medication errors both at prescribing points and dispensing points. It would most likely reduce the medication cost in a drug therapy. The likely word is used because there are several concerns on generic name prescriptions. There are several companies making generics or branded generics. The prices vary widely at least for drugs which are not under the domain of price control mechanism. In such cases, which one the pharmacist would dispense. It is obvious that the variety which gives the maximum profit would be the choice for the pharmacist. The choice of brand just gets shifted from the medical doctor to the chemist and the drug seller .

The regulation of manufacture, sale and distribution of drugs is primarily the concern of state authorities while central authorities are responsible for approval of new drugs and clinical trials, laying down the standards for drugs, control over the quality of imported drugs, coordination of the activities of State Drug Control Organizations providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

This organization deals with all new drug approvals, review of new safety information regarding approved drugs, approval and safety review of fixed-dose combinations, medical devices, and implants. All endocrine and metabolic drugs are covered by these organizations and acts. Food supplements (including many herbal products) are regulated by separate laws since they are legally not considered drugs.

In India, drug testing laboratories are located at central and regional levels which are entrusted with the job of ensuring production and availability of quality medicines.

During the years 2011-2014, the regional laboratories tested samples at 91% of the installed capacity but their overall detection rate of sub-standard drugs was only 3.6%.

The total number of samples tested was 43,387 over a period of 3 years. This number though impressive still lags significantly in terms of detection rate and especially when corrected for growth in the number of pharmaceutical companies over this period. In addition, with its manpower of 327 employees in 2012, CDSCO is grossly understaffed to perform its assigned duties of protecting the general population from sub-standard, spurious, and counterfeit medicines. The 2014 episode of death of 13 women and illness of 138 following tubectomy and prescription of poor quality ciprofloxacin is a clear indicator of the deficiencies in our system which makes available poor quality medicines.

PROPOSED SOLUTIONS

The solution to the problem of branded versus generic lies in strengthening the existing quality control structure of the country. The strategy can be two pronged with an increase in the capacity of existing laboratories and opening up of new laboratories in government colleges. Pharmacology departments of existing medical colleges can play a big role in this direction.

The public sector ("jan aushadhi" scheme, hospitals etc.,) should procure medicines from firms which quote lowest price (existing practice) along with in-house quality control reports of each batch of medicines supplied. These firms must be subject to external audit and quality control as well. Physicians should be allowed choice of writing generic or branded products as they are best placed to monitor efficacy and safety of drug therapy. Pharmacists should also be involved in informed decision making, as should members of patient organizations. With the burden of endocrinopathy increasing rapidly, the need for endocrinologists to contribute to such decision making is also important. This editorial hopes to sensitize our specialties to play a proactive role in ensuring rational use of branded and generic drugs.

~Dr Sanjay Agrawal