

Choice of better medicine in India: branded vs generic medicine

Editorial

The Indian pharmaceuticals market is the third largest in terms of volume and thirteenth largest in terms of value, as per a report by Equity Master. The Indian Pharmaceutical market (IPM) accounts for approx. 1.4% of the global pharmaceutical industry in value terms and 20% in the volume terms.^{1,2} Generic drugs are currently the highest earners within India's pharmaceutical industry, accounting for 70% of market share by revenues. Over-the-counter drugs follow at 21% of revenues and patented brand name drugs at 9%.³ Brand name medicine is originally discovered and developed by a pharmaceutical company. Brand name medicine is approved by FDA by submitting a New Drug Application along with data regarding proof of characteristics of dosage form, manufacturing, chemistry, stability, efficacy, safety, labeling and packaging. After approval by FDA only, the innovatory company can exclusively market this brand name medicine for a period of patent protection (about 20 years or as specified). Brand name medicine is generally sold at high cost to cover expense in research and development of drug. Branded medicines are strongly promoted through doctors and chemists, which add to their retail prices. A generic medicine is one that is comparable to an innovator medicine in dosage form, strength, route of administration, quality, performance characteristics and intended use. When patents or other periods of exclusivity on brand-name drugs are near expiration, manufacturers can apply to the FDA to sell generic versions by separate name called branded generic. If drug is manufactured and sold by its original name is called pure generics. For both, submission of Abbreviated New Drug Application with data regarding bioequivalence study as a proof that the generic version deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug. All other data require are same as innovator drug product except preclinical and clinical data regarding safety and efficacy of medicine. Generic and branded drugs may be identical in formulations but differ in certain other characteristics such as shape, release mechanisms, packaging, excipients, expiration date/time and minor aspects of labeling and storage conditions. Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act allowed for the approval of generic copies of many approved drug after the patent had expired. As the cost of development is not involved Generic medicine is much cheaper than the branded one. In India, 90% of branded generics share in the ~1-lakh-crore market.⁴ India is the largest provider of generic drugs by exporting in more than 200 countries with the 20 per cent of global exports of generics in terms of volume. With flourish of generic market, now battle for better drugs is going on in India.⁵

The global generic drugs market is expected to grow at a compounded annual growth rate of 10.53% from 2016 through 2020. In fact, according to a report, the global generic drugs market will benefit from the patent expiry of drugs worth \$150 billion by 2020.⁶ This will attract pharma companies all over the world to produce generic medicines. Prescribing by generic names is justified because if brand names are used and that particular brand is not available in the drug store, the pharmacist will have to refer drug indexes like CIMS etc. (CIMS-Current Index of Medical Specialties) to find out

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the ingredient and then dispense from the available stock. This will lead to waste of time and may also lead to errors in case the wrong drug ingredient is dispensed.⁷

India is densely populated country. Drug pricing is a major issue in India. In India, where very few people have health insurance, 70% of Indians pay for healthcare expenses out of their own pockets. With the rising healthcare costs, the interest in generic drugs has increased almost all over the world whether it is a rich or a poor country. Also, there is a big difference between generic and brand name drugs in India. India is well known for importing low cost quality generic medicines to more than two hundred countries in the world. At home, however, India faces the challenge of equal access to affordable and quality essential medicines for its own population. Drugs and Cosmetics Act, 1940, Drug Price Control Order 1995 regulate quality and price control of drugs respectively in India. National Pharmaceutical Pricing Authority (1997), which is presently working under the Department of Pharmaceuticals (DoP) in the Ministry of Chemicals and Fertilizers has been entrusted the responsibilities of drug policy, medicine price control, monitoring of drug prices and related affairs. Central Drugs Standard Control Organization (CDSCO) under Ministry of Health and Family Welfare is the main authority controlling drug related issues in India. In India, poor accessibility and affordability of people, impose use of generic drugs to minimize cost of treatment. Government of India started several attempts in this direction. Department of Pharmaceuticals, Government of India, had launched the 'Jan Aushadhi Campaign', in April, 2008, to provide quality generic medicines at lower prices than their counterpart branded ones available in the market. In the 2016-2017 budgets, Government of India has made the goal of opening of 3000 "Jan Aushadhi Stores" across the country.

On October 12, 2012 Government of India issued directions that the drugs will be sold under their generic name rather than their brand names.⁸ This directive created confusion regarding choice of branded generics because almost 90% drugs in India are known by their branded generic name. Narendra Modi, Prime Minister, government of India plans to make it mandatory for doctors to prescribe pure-generic drugs, instead of branded generics as they do now. The health ministry of India has now started working on amending the Drugs

and Cosmetics Act to this effect. The health ministry has recently issued a draft gazette notification making it mandatory for pharma companies to carry generic name of drugs on packs that is at least two fonts larger than the brand name. Besides, the ministry has also issued orders to the Medical Council of India (MCI), state governments and all central government hospitals asking them to ensure that doctors write prescriptions with generic names of medicines in legible hand writing.⁹

Barriers to move towards generic drugs in India

- A) In developed countries such as the US, only patented drugs are sold under a brand, which is marketed through their ties to doctors. Off-patent drugs are sold only as pure generic, without using any brand name. It helps in making pure generics cheaper. But in India, most of the generic drugs are sold as their brand name (brand generics).
- B) Commission on sales of brand name drug is much higher for everyone in the supply chain. Since the generics are priced considerably lower, the revenue earned by everyone in the supply chain is lower. So brand sellers in India could prevent government's move to generics.
- C) Despite stringent price control, big pharma companies manage to spend exorbitantly on marketing and branding of their drugs. Since advertisement of prescription medicines are not allowed in India, companies or medical representatives push their products through doctors, chemists and distributors in lieu of freebies, junkets and incentives.
- D) In India, Quality of generic drugs is not considered at par as brand name drugs. For obtaining quality standard of brand drugs, generic producers will have to invest in equipments and necessary approval process which may increase the cost of generic drugs.
- E) Also, in developed countries like U.S., 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. This can reduce sells of economic generic drugs.
- F) If the doctor prescribes only a generic name, it will be left to the chemist to decide which particular brand to push. Further, Generic producers may supply with questionable quality in shortage unless government frame policy with appropriate penalties. Also, proposal of writing generic name in prescription will make difficult to prescribe combination drugs or drugs with multiple ingredients.

In addition to this, guidance of physician is required while patient

switching to generic drugs from brand name drug with narrow therapeutic index (antiepileptics, antiarrhythmic, thyroid hormone, lithium, etc). Monitoring is also required for first couple of weeks afterwards. Some patients may have allergies or intolerances to excipients such as lactose, gluten, sulfites or tartrazine. Although the active ingredients are the same, the excipients (inactive ingredients) may differ. This is only important in rare cases when a patient has an allergy or sensitivity to one of the excipients.

In present scenario, Generic drug is looking best option for India but progressive changes require in mentality of Indian people to adopt this truth. Besides this, there is greater need for a harmonized drug regulation globally for overall growth of pharmaceutical sector. Major goal of patient care should be accessibility and availability of quality health care service and infrastructure. Incentive and tax relief to research are require to promote betterment of human health. Through use of cost effective and sustainable technology and methods, entrepreneurs must reduce the cost of drugs.

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Conflict of interest

Author declares that there is no conflict of interest.

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