

Generic medicines in the Indian scenario – What are we expecting?

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The recent buzz on generic medication use in India, need to promote their use and MCI notification on code of ethics that the doctors should write only generic prescriptions, made me think about the purpose of the whole exercise. What do we mean by generic medicines, why is it important, what is the understanding of the public and the physicians about them are key question I would like to address.

India's Pharmaceutical market grew at 15.7% during December 2011. Globally India ranks third in terms of manufacturing pharmaceuticals product by volume.^{1a} The Indian pharmaceutical industry is expected to grow at a rate of 9.9% till 2010 and after that 9.5% till 2015. The Indian pharmaceutical market is expected to touch US \$72 billion sale by 2020 from US \$11 billion. The market has the further potential to reach US \$70 billion by 2020. India ranks 17th in terms of exports its product to more than 200 countries around the globe including highly regulated markets of USA, Europe, Japan, and Australia. The paradox is that despite producing huge pharmaceutical products, India has been identified as one among several developing countries that are regarded as the source of counterfeit medicines by the organisation for Economic Cooperation and Development (OECD).⁽¹⁾

A generic drug is a pharmaceutical drug that is equivalent to a brand-name product in dosage, strength, route of administration, quality, performance, and intended use. The term may also refer to any drug marketed under its chemical name without advertising, or to the chemical makeup of a drug rather than the brand name under which the drug is sold.⁽²⁾ Original Brand or the Innovators Brand is supposed to be the branded version of the generics, which is patented and priced higher as the addition of the Research and Development (R&D) cost is added to the drug.

There is a lot of confusion surrounding the nomenclature in India as we see the terms Branded generics, most commonly sold generics and low cost generics in the literature. The reason for this is the patent act 1970 which removed product patent for 15 years as in the west and allowed process patent for 5-7 years. This allowed the Indian pharmaceutical companies to reverse engineer the drugs changing the process of making the drug and produce low cost generics.⁽³⁾ The process helped the Indian Pharmaceutical industry growth in making it among the top exporter of the generic drugs worldwide. In the local market this lead to new version of Branded drugs also called branded generic where the generics were branded by the company and marketed in

the country adding the additional price of branding and marketing to the drugs. The marketing strategy promised good standards of production and quality of the drugs both to doctors as well as consumers alike. The same company manufactures the generics with the chemical name and the brand name (requiring separate licenses); but the generics are marketed to distributors and the retailers at a huge margin. The license for generics is granted when a drug has shows bio-equivalence of 20% higher or lower than the original brand; that means to say that different generics have different percentages of bio-equivalence ranging from 80% to 120%. It is argued that this difference in the generics might be cause dyscontrol of long standing illness where maintenance of therapeutic drug levels is crucial. In 2005 the "Patent amendment act" made reverse engineering or copying of patented drugs illegal after January 1, 1995. The Act allowed for only two types of generic drugs in the Indian market: off-patent generic drugs and generic versions of drugs patented before 1995. At present, nearly 97 percent of all drugs manufactured in India are off patent and therefore will not be affected by this Act.⁽³⁾

The policies are made to make the medical services more affordable. India's health care is one of the most neglected areas, total expenditure on health in India was 4.3% of GDP in 2000 and 3.9% in 2011. In 2011, public expenditure on health was 30% of total expenditure on health in India; which is nowhere near to the 46% in Brazil, 48% in US, 56% in China, 60% in Russia and 83% in UK. Our medical care is more dependent on private sector and Out of the Patients Pocket expenses. In the year 2011, 60% of total expenditure on health in India was from out-of-pocket (OOP) resources, which was 68% in the year 2000.⁽⁴⁾ It is therefore very important to make medicines more affordable. Such benefits might be enormous when it comes to life saving drugs like chemotherapeutic agents treating cancer.⁽⁵⁾ One has to keep in mind that the comparison in the Indian market is not with the original versus generic it is between the branded generic with the generic. When we compare the price difference between the generic versus their branded counterparts, the research in 6 centers across the country has shown that the difference in price to patient is around 25 to 40% where as for the retailer the margin is in the range of 300 to 1000%.⁽⁶⁾ It was also sometimes found that the branded version of one company was cheaper to the generic version of other company. This brings us to the point of drug price control act that has from time to time brought in many essential drugs into its purview and tried to control the

Maximum Retail price of the Drugs. However there is no uniformity in the price control at the level of retailer, even though there is a margin specified under the act the companies by pass it by giving free products or cash discounts to the retailer to push their products. This benefit does not reach to the consumers. So there is no guarantee that generic medicines in India are cheaper than their branded counterparts.

The research in various countries have shown that generic drugs are as good as the Branded original in the bio-equivalence and efficacy.⁽⁷⁾ Most of the studies on Anti epileptic drugs have also shown that the incidence of break through seizures is not increased on changing to generics.⁽⁸⁾ However the acceptance on the use and prescription of generic drugs is low. Studies on attitudes of physicians on the prescription of generic drugs have shown that, generally physicians were neutral to slightly supportive on the use of generic medications. However, the extent of their neutrality and acceptance varied substantially with several factors.⁽⁹⁾ The confidence on the regulatory authorities in ensuring the quality, safety and efficacy of generic drugs is low.⁽¹⁰⁾ Patient related factor where the patients want the best treatment available versus the cost that can be borne by the patient. Drug related factor where being cheaper than their branded counterparts raised the concerns of the physicians about their quality, safety and effectiveness, especially in the presence of heavy and successful promotional activities from brand name industry. These concerns were stronger in a few classes which are considered by physicians to be critical dose drugs. Indian studies have also shown that generic drug prescription in the private sector is very meager, even in public sector the percentage is way below 30% mainly due to non-availability of the drugs. One should also focus on the one more factor that is important; the prescription patterns of physicians in India have shown that there are multiple unnecessary medications and illegible prescriptions. The knowledge of the pharmacist about the brand names is also very poor and most of the Indian Pharmacies are manned by non-qualified pharmacists. Therefore more problematic situation arises as there are thousands of brand names which sound similar and look similar, if a pharmacist dispenses Methyl Prednisolone for Methyl Phenidate the results would be very dangerous. There have been instances where it proved fatal when a hypoglycemic agent was given for allergy as the name sounded similar. The acceptance of the generic medications among public is also low, even though there has been constant uproar and encouragement by the governments on generic medicines their success is low. India's ambitious project "Jan Aushadhi Scheme" is not able to achieve, what it is meant to achieve till date. As per the Standing Committee on Chemicals and Fertilisers report in March 2015, till date only 170 Jan Aushadhi stores have been opened, of which only 99 are functional.^(11,12) Patients often rely on the physician's opinion regarding the

medication and do not want to take any chances on changing the brand name prescribed and if an option of generic medication is given to the patient, he wants the doctor to take a call on what is best.

All the stakeholders need to take a unified action to make health care cost or at least drug cost to the minimal. First of all as the Code of ethics MCI notification requires to write the name of medication in capitals along with the generic name, it should be strongly implemented. The physician even prescribing a brand name should also mention the generic name to aid in easy substitution by the pharmacist where required. The doctor should think about the best possible affordable care for the patient. The price control act should also have more clauses for the retailers to pass on the benefit to the consumer and maintain a uniform pricing for various generics for a drug. The public sector should focus on more allocation of budget for procurement of the essential drugs. The awareness of the physicians and public should increase about the knowledge of Generic Drugs. Generic drugs should be made available in most of the retail outlet and promoted rather than trying to make them available at special outlets.

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