

# The Myth of Branded Generics

INJETI SRINIVAS

The pharmaceutical market in India is unique in that it is dominated by “branded” generics which enjoy a price premium though they are not superior to “unbranded” generics in either pharmacopoeia or therapeutic value. Aggressive marketing of branded generics has led to higher prices, irrational fixed dose combinations and concentration in the industry. It is high time India moved towards a de-branding of generic drugs.

This article is written in the author's personal capacity and the views expressed are his own and not that of the Government of India.

Injeti Srinivas (*injeti.srinivas@nic.in*) is Chairman, National Pharmaceuticals Pricing Authority.

Generics have made drugs more affordable the world over because of the intense competition they bring along with them. Unlike a brand name drug, which is protected by exclusive marketing rights under a commercial patent, its generic version, which is usually manufactured and marketed by several competitors after expiry of the originator patent, sells at a fraction of the original price, thereby benefiting the consumer immensely.

In pharmacopoeia, a generic drug has the same active pharmaceutical ingredient(s) (API) as the originator drug and works alike in dosage, strength, performance and use. In the United States (US), bioequivalence measures of generic drugs approved by the Food and Drug Administration over a 12-year period of 1996-2007, involving 2,070 bioequivalent studies, were found comparable with those of their corresponding innovator counterparts. In India, the position is no different. All drugs, including generic versions, are subjected to identical statutory requirements, inspections and approvals. All drug manufacturers have to conform to the Schedule M Good Manufacturing Practices prescribed under the Drugs and

Cosmetics Act, 1940. They must also meet the same labelling requirements and quality standards, and possess necessary manufacturing and sale licences. Any drug that fails to meet the pharmacopoeia specifications, including quality standards, is treated as a spurious drug and is not allowed to be sold in the market.

A study of spurious drugs by the Ministry of Health and Family Welfare (2009-10) found only 11 out of 24,136 drug samples failing the quality test, which comes to just around 0.046%. Similar studies conducted by the state drug controllers (2001-08) found only 0.3% to 0.4% of the samples to be spurious. More recently a comparative evaluation study on price and quality of generic drugs, including Jan Aushadhi, and their reputed branded-generic counterparts was done by a team of experts and it was found that they were identical in terms of identification, uniformity of weight, assay, uniformity of contents and dissolution. Hence, the common misconception that unbranded generic drugs are of poor quality is misplaced. Therefore, most countries take steps to promote the use of generic drugs, as they are both cost-effective and clinically effective.

## Types of Generics

Typically, when a brand name drug goes off patent, its market value erodes by 30% to 40% initially and ultimately by 90% or more because of intense competition.

The us, which has the largest pharmaceutical market in the world, around \$325 billion, which is one-third of the global pharmaceutical market, leads the way with generics accounting for 84% in terms of volume of sales and only 28% in terms of sales value. The position is not very different in a number of countries of the European Union (EU) and OECD (Organisation for Economic Co-operation and Development) countries where the average annual growth in pharmaceutical expenditure in real terms is falling due to generic competition. But, on the contrary, in India the share of generic drugs, which are normally referred to as “trade generics”, is barely 8% of the Rs 80,000 crore domestic pharmaceutical market. An overwhelming 90% is accounted for by the so-called “branded generics”, a share that is peculiar to India. And the share of “unbranded generics” as well as brand name or patented drugs is insignificant; say about 1% each.

The difference between branded generics and trade generics has more to do with marketing strategy than anything else. Whereas branded generics sale is doctor-led or prescription-driven, trade generics sale is retail-led or chemist driven. Trade generics are much cheaper than branded generics because drug companies do not incur direct promotional expenditure and instead provide a higher trade margin for the retailer to push the product. For the sake of convenience, we can club the two because both sell under their own brand names. Ironically, many reputed drug manufacturers have both branded generic and trade generic businesses and push the same pharmaceutical product (may be with some differences in excipients but no real therapeutic gain) through both channels in order to capture as much of the market as possible. The unbranded generics, on the other hand, sell under the chemical name, and their sales in the retail market are largely confined to Jan Aushadhi, which has hardly any presence in the country’s pharmaceutical market. The main sources of demand for unbranded generic drugs are government agencies, which usually procure drugs in their generic name for the public health system. But in the absence of

comprehensive data in the public domain it is difficult to estimate the quantum and value of such sales.

### Premia on Branded Generics

The concept of branded generics appears to be a contradiction in itself because it gives neither the price advantage that accompanies a generic product nor the therapeutic advantage associated with a brand name product. The repeated claims of higher efficacy made by drug companies are only self-proclaimed, as they lack the endorsement of the Central Drugs Standard Control Organization (CDSCO), which is the competent body in the country to make such a decision.

In the United Kingdom, the National Institute for Health and Care Excellence, which is popularly referred to as NICE, is responsible for measuring and certifying the therapeutic value of a pharmaceutical product, including those based on non-API related novel delivery systems, etc, in order to promote value-based pricing. Similarly, in Germany it is done by an organisation called the ANMOG. In India too drugs involving a new delivery system developed through indigenous research and development efforts are exempted from the application of price control measures, provided they have the approval under the Drugs and Cosmetics Rules. But in the absence of any such certification by an authorised body, it is only logical to conclude that the so-called distinction between different brands of a branded generic drug as also that between a branded generic and an unbranded generic drug has little to do with pharmacopoeia, and is purely a marketing strategy to extract premia on brand considerations.

The marketing strategy of branded generics is based on two factors, namely, aggressive promotional measures adopted by drug companies, which are aimed at influencing the doctor’s prescription behaviour; and, second, the severe information asymmetry that exists between the doctor and the patient as a result of which the patient is unable to take an informed decision regarding a cost-effective treatment. Although branded generics are not totally unknown in developed countries, their presence is largely confined to

over-the-counter (OTC)/non-prescription drugs where consumer choice does exist and market share is determined by market competition. In India, on the other hand, branded generics are not confined to OTC drugs and the bulk of them are prescription drugs where the consumer has little choice in drug selection.

### No Difference

Hence, the difference between a branded generic and an unbranded generic drug is only in form and not substance. Whereas an unbranded generic drug is sold under the chemical name, a branded generic is sold under its brand name or trade name, and there are scores and sometimes hundreds of branded versions for the same generic formulation, which add to information asymmetry. Hence, to assume that a costlier brand is of a higher quality than a cheaper brand or even the unbranded generic version when all of them are required to meet the same specifications and standards is completely wrong. Moreover, maintenance of quality is the responsibility of the manufacturer and it does not necessarily go with the brand name the drug carries. The oft-repeated defence of reputed manufacturers that they maintain higher standards than those prescribed by pharmacopoeia also does not hold water because pharmacopoeia standards are enough from the viewpoint of therapy and safety of the patient. As such, the so-called higher standards cannot justify unreasonably higher pricing without any therapeutic advantage to be gained by the patient.

When different brands of the same generic formulation are therapeutically identical to each other and safely interchangeable with each other, the huge price differential between them is counter-intuitive. In many cases a branded generic drug sells at a price which is three to four times higher than that of the minimum priced branded version, and 10 times or more than its unbranded generic equivalent. This may not be very different from the huge price differential observed between a generic drug and a brand name or patented drug in general, but unlike the latter where the premium is charged for proprietary knowledge backed by therapeutic gain, in the former it is

primarily on account of supplier-induced brand value. Ironically the same drug that is exported to developed countries under its generic name is often sold in the Indian market as a premium branded product, which exposes the double standards of the industry.

### Domination in Market

Patients in India are unable to derive the full price advantage from generic competition because branded generics dominate the pharmaceutical market on the make-believe projection of therapeutic competition. The prices of drugs in India must be seen in the context of the purchasing power of the common man and not compared with those prevailing in other countries in absolute terms. There is mushrooming of brands, including countless fixed drug combinations (FDCs) in India. Over 40% of drugs sold in India are FDCs whereas it is less than 20% in well-developed pharmaceutical markets. Many of the FDCs sold in the country are believed to be irrational, which needs to be tackled with better regulation and enforcement efforts. We have more than

20,000 brands in India, which when differentiated by strengths and dosages can go up to 1,70,000, out of which about 90,000 have active movement in the retail market. Sadly, in many cases the same manufacturer sells the same formulation under different brand names in different parts of the country at different prices, leading to market concentration through brand proliferation.

The Hathi Committee, way back in 1975, recommended a phased de-branding of generics, which was reiterated by the Pronab Sen Task Force in 2005, and more recently by the V M Katoch Task Force in 2011, which recommended that all single-ingredient drugs must be sold only under a generic name. This may require the drug controllers to grant marketing approval to generic names and not brand names. It may also require an amendment of the Trade Mark Act, 1999.

The very fact that in all other essential commodities, the branded segment is minuscule when compared to the unbranded segment, whereas in the case of the pharmaceutical sector it is the other way round shows that the consumer is not

the king in this very important sector. What makes it worse is that, bulk of the expenditure on medicines is borne by the general public as out-of-pocket expenses because not much government support is available for outpatient care.

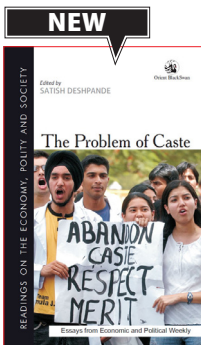
Another offshoot of the market distortion caused by branded generics is the heavy market concentration where the top 10 companies account for 41% and 100 companies for 95% of the industry turnover. Since the big pharma companies' manufacturing capacities are to a large extent utilised to meet their own export obligations, valued at around \$14-15 billion, they are heavily dependent upon the 7,000 odd small and medium enterprises to meet their requirement for the domestic market through contract manufacturing/loan licence arrangements.

The Indian pharmaceutical market is also highly concentrated at the drug formulation level; 2,230 out of 2,583 (86%) commonly used drug formulations have a high concentration, accounting for nearly 50% of the entire domestic pharmaceutical market. Pharmaceutical product differentiation on brand considerations

## The Problem of Caste

Edited by

**SATISH DESHPANDE**



Pp xi + 425 Rs 595  
ISBN 978-81-250-5501-3  
2014

Caste is one of the oldest concerns of the social sciences in India that continues to be relevant even today.

The general perception about caste is that it was an outdated concept until it was revived by colonial policies and promoted by vested interests and electoral politics after independence. This hegemonic perception changed irrevocably in the 1990s after the controversial reservations for the Other Backward Classes recommended by the Mandal Commission, revealing it to be a belief of only a privileged upper caste minority – for the vast majority of Indians caste continued to be a crucial determinant of life opportunities.

This volume collects significant writings spanning seven decades, three generations and several disciplines, and discusses established perspectives in relation to emergent concerns, disciplinary responses ranging from sociology to law, the relationship between caste and class, the interplay between caste and politics, old and new challenges in law and policy, emergent research areas and post-Mandal innovations in caste studies.

**Authors:** Satish Deshpande • Irawati Karve • M N Srinivas • Dipankar Gupta • André Béteille • Rajni Kothari • Kumkum Roy • Sukhadeo Thorat • Katherine S Newman • Marc Galanter • Sundar Sarukkai • Gopal Guru • D L Sheth • Anand Chakravarti • Carol Upadhyia • Ashwini Deshpande • Meena Gopal • Baldev Raj Nayar • Gail Omvedt • Mohan Ram • I P Desai • K Balagopal • Sudha Pai • Anand Teltumbde • Surinder S Jodhka • Ghanshyam Shah • Susie Tharu • M Madhava Prasad • Rekha Pappu • K Satyanarayana • Padmanabh Samarendra • Mary E John • Uma Chakravarti • Prem Chowdhry • V Geetha • Sharmila Rege • S Anandhi • J Jeyaranjan • Rajan Krishnan • Rekha Raj • Kancha Ilaiah • Aditya Nigam • M S S Pandian

**Orient Blackswan Pvt Ltd**

www.orientblackswan.com

Mumbai • Chennai • New Delhi • Kolkata • Bangalore • Bhubaneswar • Ernakulam • Guwahati • Jaipur • Lucknow • Patna • Chandigarh • Hyderabad

Contact: info@orientblackswan.com

and supplier-induced prescription-driven demand has led to strong entry barriers and heavy market concentration in most therapeutic groups where quite often the market leader is also the price leader. The adverse selection behaviour associating higher price with better quality is a direct outcome of information asymmetry and market concentration.

### Measures Needed

A number of measures are required to reverse this huge anomaly and promote generic drugs in the country in a big way.

First, there is a need for supportive legislation and regulations that (i) make prescriptions in generic names mandatory through standard treatment guidelines (deviation should be permitted only when supported with full justification); (ii) provide a legal basis for generic substitution by pharmacists; and (iii) provide for mandatory de-branding of generic drugs in a phased manner. Second, quality assurance capacity needs to be enhanced as also the procedures to demonstrate bioequivalence (this needs to be strengthened considerably), apart from enhancement of

national quality assurance capability, including drug manufacturer and drug outlet inspection capability. Third, professional and public acceptance needs to be promoted through focused efforts. Fourth, widespread information dissemination on drug prices should be ensured. And finally, economic tools such as reference pricing, a reimbursement policy, price control, and incentives to drug industry should be used to promote generic drugs. Only then can we fully achieve the larger objective of “Affordable Medicines for All”.