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Research Article

A STUDY ON THE PURCHASE DECISION BEHAVIOR OF DOCTORS IN INDIA WITH RESPECT TO PERCEPTION ON QUALITY OF GENERIC DRUGS

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A B S T R A C T

Medicines are crucial building blocks of the health care system and contribute to health and well-being of individuals and a nation. 4p's of marketing, i.e. product, place, price, and promotion forms the foundation for the entire structure of health care marketing. Understanding the behavior of doctors as consumers gives an insight into some of the psychological aspects of marketing of medicines. The perception of high quality is the most important product attribute for medicines needed to gain the doctors trust, which is missing with generic drugs in India. Perception of poor quality of the generic drugs is preventing the Indian doctors to prescribe the same to their patients. Yet awareness and trust on quality of generic drugs are still questions to be answered to convince the Indian doctors to prescribe generic drugs. Since there is no systematic and universal health care coverage plans in most the states, out-of-pocket expenditure on medicines is estimated to be around 95 percent of hospitalizations, and is a known driver of poverty among the Indian poor. Though India is famed as "pharmacy of world" and feeding the needs of the entire world with high quality generic drugs, the Indian pharma industry fails to provide the same benefits for the needy Indians who cannot afford expensive branded medicines. The Prime Minister Modi's initiative of the Pradhan Mantri Bhartiya Janaushadhi Pariyojana is an important policy decision to reduce out-of-pocket expenditure on medicines. Medical Council of India has notified that all physicians should prescribe drugs with generic names only, not with brand names.

INTRODUCTION

The quality and merits of branded drugs versus generic drugs is attracting the attention of all doctors. After the Prime Minister's speech in Surat this issue has triggered a heated debate among physicians, pharma professionals, national media and health care activists. The Prime Minister has mentioned bringing a law to ensure that doctors should prescribe only generic names of drugs not the brand names. It is aimed to help the poor patients to access generics, the cheaper versions of branded drugs. The law proposed by the government will make it illegal for Indian doctors to write a prescription with the brand name of the drug, forcing them to mention only the generic chemical name of the drug.

The recent directive issued by Medical Council of India (MCI) as a follow-up of the government policy to ensure the prescription of low-cost and good quality generic drugs to poor patients has created a wave of a stir, not only in the medical fraternity but also in the minds of regular customers.

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While the MCI circular states that doctors should prescribe only generic names, the Indian Medical Association (IMA) says prescribing generic drugs should be one of the options and the choice should be left to the discretion of the doctors. On the issue of prescribing of generic drugs only policy, confusion and ambiguity prevail between the MCI and the IMA.

Before the pros and cons of the government directive can be studied in detail, it is important and imperative to understand the very basics of the issue. What is the definition of the 'generic medicine' and the attributes of the 'generic medicine'. How a generic medicine is different from other variants available under different brand names in the market?

Consumer behavior

Gone are the days when the manufacturers could produce anything they like, fix a price and sell it to the consumers. Now it is the consumer who's buying preferences and choice decides what should be manufactured. In the consumer driven markets, consumer will decide the quality of the product to be produced, the price of the product and at what quantity it should be produced and how it should be marketed.

The marketer has to take into consideration various factors while deciding on producing and marketing a product as consumers have diverse preferences. The task of manufacturer and marketer becomes difficult and therefore it is very important to understand the consumer behavior. In the field of pharmaceutical marketing as the target customer is not the end user, but the influencing person, the doctor, understanding consumer behavior of a doctor is still an arduous task. Today the doctors have more product options as many generic medicines are available with lower prices and challenge the original invent branded product in the market.

Definition of consumer behavior

The term consumer behavior is defined as the behavior that consumers display in searching for purchasing, evaluating and dispensing of products and services that they expect will satisfy their needs. The behavioral sciences that have made significant contributions to the study of consumer behavior are economics, sociology, psychology, political science and cultural anthropology.

Factors which influence consumer behavior

Discussions are focused on the need that marketing has to be consumer oriented. Marketing should be concerned with the methods to satisfy the needs, wants, and demands of the consumer.

Studying the following consumer behavior and psychological factors are important and critical for companies for the success of their products in the competitive market.

Cultural Factors

Culture is the fundamental determinant of a person's needs, wants and demands and related behavior.

Social Factors

The social factors include reference group, family, social status and role.

Personal Factors

Various individual and personal factors like age, stage in the life cycle, occupational, economic condition, lifestyle, personality and self concept will influence consumer behavior.

Physiological Factors

The major physiological factors are motivation, perception, learning, belief and attitude.

Psychographic Factors

It is more important to know what sort of needs a person has. It helps while dealing with the psychographic behavior of the consumer.

The consumer buying decision process

The consumer buying decision process is a five-stage purchase decision process as explained in the following steps.

Stage I: Problem recognition
Stage II: Information search
Stage **III :** Evaluation of alternatives
Stage IV: Purchasing the product
Stage V: Post-purchase evaluation

Before a consumer makes a choice to buy a product, the consumer evaluates different alternatives that are available. During this process various product attributes that the consumer associates with each product option, can be evaluated and its importance is determined.

The evaluation of alternatives may either be very extensive and time-consuming at times and rather narrow and fast at other times. The consumer will narrow down the alternatives with the help of his own personal heuristic rules. The act of the actual purchase of a product is only one stage in the entire buying decision process and may not be the first stage. Not all consumer buying decisions include all five stages in the process. Not all steps in the decision processes once initiated will lead to an ultimate purchase. The individual consumer may terminate the buying decision process at any stage.

Situational influences like circumstances, time, and location will affect the consumer buying decision process. Situations can influence a consumer's actions at any stage of the buying decision process and can shorten, lengthen, or terminate the buying process.

Consumers may create different rules that will help in and facilitate their decision-making. These rules are of various nature and represents different assumptions and mindsets. It may be related to their personal beliefs about products, brands and companies. They may associate product familiarity with product quality, or interpret product quality based on indications. It is very common for some consumers tend to judge a book by its cover. It is common to associate high price with good quality.

In some cases the buying behavior will turn into a habit where the consumers need not put any effort into making a decision. Such a buying habit stems from the brand loyalty, where the consumer feels strongly, and positively about certain qualities of a brand. In habitual buying the consumer makes consciously a choice to buy a particular brand of product. A personal connection and bond to the brand will be developed over some time and reinforces the habitual buying behavior and it makes the consumer less prone to switch to any other new brand.

For some other consumers the habitual buying behavior develops from inertia when the consumer is reluctant to put any effort into the decision-making process. Because there is no strong personal connection or bond to the product or the brand, the consumer is prone to switch to another new brand. The reason for a change to new product may be due to better availability or price and the opportunity to buy the new product easily.

The purchase can be spontaneous, where the purchase is not planned upon. It may due to the consumer is led to buy the product because of a re-minder, or due to any other reason that incite the consumer to buy the product. Companies regularly use advertisements to connect their products with some emotions and feelings, because these aroused feelings can influence the consumer to choose a certain product over another. Due to this reason the consumer develops behavior of buying a product out of habit.

Introduction to Indian pharma industry "The World's Pharmacy"

India is reputed as the "world's pharmacy" because of its high quality generic drugs. India is one of the leading countries to export world-class generic medicines to more than 200 countries. Out of every 7 medicines consumed in the world, 1

is from India. The March 2017 report of 'India Brand Equity Foundation (IBEF) states that Indian pharmaceutical sector accounts for about 2.4 per cent of the global pharmaceutical industry in value terms, 10 per cent in volume terms and is expected to expand at a Compound Annual Growth Rate (CAGR) of 15.92 per cent to US$ 55 billion by the year 2020, from US$ 20 billion in the year 2015. With 70 per cent market share in terms of value, generic drugs constitute its largest segment. Over the Counter (OTC) medicines and patented drugs constitute the balance 21 percent and 9 percent, respectively. Branded generics constitute around 90 percent of the generic market.

In India any person can modify and manipulate any drug without legal implication or ramifications. This led to the increased demand and share of branded generic drugs. With more than 90 percent of the country' s pharma market is dominated by branded generic drugs, Indian branded medicines are 1 lakh 20 thousand crores in terms market size. ASSOCHAM estimates project that India will be among the top three pharmaceutical markets with incremental growth by the year 2020. India's strength within the pharmaceutical sector can be seen in the sheer number of pharmaceutical manufacturing plants in the country, which numbers approximately 10,500. Outside of the U.S., India boasts the largest number of U.S. Food and Drug Administration (FDA) compliant pharmaceutical manufacturing plants. In addition India has 1,400 plants that have been approved by the World Health Organization Good Manufacturing Practices (WHO GMP) and 253 by the European Directorate of Quality Medicines (EDQM).

It is an irony that despite being the 4th largest producer of pharmaceuticals, and catering to the needs of 20 percent of the global requirements for generic medicines, India is still unable to ensure access to many modern medicines to a large section of its own population. The generic drug manufacturers are need to quickly adapt to 'low margin – high volume' business model, leveraging economies of scale, and accepting the stark reality as was expressed in an article published in Forbes 'the age of commodity medicines approaches'. Even otherwise, what's wrong in the term commodity, either, especially when generic medicines have been officially and legally classified as essential commodities in India.

Why preference should be given to generic drugs

India has the world's highest rate of tuberculosis; the second highest number of diabetes cases after China; the third largest incidence of HIV, with 2.1 million cases; and very high numbers of reported malaria cases at over 2 million; and millions are affected by some form of psychiatric disorder. Maternal mortality rate, at 178 per 100,000 live births, is also a concern. The six diseases were selected due to their high prevalence in the country.

Even after 70 years of independence, we have around 60 percent of the population who are not able to afford the branded medicines. Look at the dichotomy; on one hand 6 out of 10 Indians do not have access to basic medicines, whereas India is within the first four countries of the world in producing high quality generic drugs and exporting the same to the entire world.

Economic burden for poor patients

In India more than 70 percent of the population live in the rural areas. Out of such population around 35 percent lives in below poverty line or close to it. India is featured as one among the countries with the highest out-of-pocket expenditure on health care. The National Health Policy admits that 63 million people are pushed into poverty annually owing to health care expenses alone. As per the recent National Sample Survey Office Survey on Health Care in 2014, medicines emerged as a major component of total health care expenses, contributing to 72 percent in rural areas and 68 percent in urban areas. In India, 'Out of Pocket (OoP) expenditure for health care being around 70 percent is one of the highest in the world.

A study by the World Bank conducted in May 2001 titled, "India Raising the Sights Better Health Systems for India's Poor" indicates that out-of-pocket medical costs alone may push 2.2 percent of the population below the poverty line in one year. Cost of medicines constitutes a large percentage of the total medical costs of an individual, as over 95 percent of the Indian population is not covered by any medical insurance; such medical expenditure continues to haunt the common man. The proposed law is intended to improve affordability of quality medicines in the country of 1.2 billion people, where the majority live on less than $2 a day. It is being in circulation that some doctors are prescribing branded drugs because they receive some incentives from the pharma companies. The use of generic drugs, which are no different from the branded drugs in terms of quality will certainly reduce the rising cost of health care and millions of poor among the poorest will get benefited.

What is a generic drug and why the same medicine has different brand names

It's like groceries where different companies can produce the same commodity or product, then market and sell the same with different brand names to consumers. Medicines are also can be produced and sold as different brands or as generics.

Since the MCI has no specific official definition of generic drugs in India, we can refer the USFDA definition which describes a generic drug "as identical or bio equivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use".

The WHO defines a generic drug as "a pharmaceutical product, usually intended to be interchangeable with an innovative 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 medicines are developed when patent and other exclusivity rights get expire. To ensure the therapeutic efficacy of a generic drug, it must be pharmaceutically interchangeable and bio equivalent to the original patented drug.

To qualify the tag of a generic drug with global quality standards the generic drug must adhere the following conditions.

- A generic drug must contain the same active ingredients as the innovator drug.
- It should be identical in strength, dosage form, and route of administration.

- It must be bio equivalent, as a marker for therapeutic interchangeability.
- A generic drug must meet the same batch requirements for identity, strength, purity and quality.
- All the generic drugs must be manufactured under the same strict standards of GMP required for innovator products.

Most of the medicines are chemicals

In medicines the active ingredient is a chemical that makes the medicine to work. The active ingredient names are scientific and quite difficult to remember and pronounce. A company therefore gives their medicine another easier to say or memorable brand name under which the medicine is marketed and sold. Generic drugs are known by the name of its chemical composition only. Paracetamol is a generic drug marketed with brand names like Calpol or Crocin.

Dr. Suresh Sarvadekar, consultant, Ministry of Medical Education, Maharashtra said: "Most medicines are chemicals and the chemical name is a generic name. Generic A can be called equivalent to the original patented drug B, only if it is bio equivalent [reaches blood at the same time with the same blood levels] and a therapeutic equivalent. In the Indian context, it is important and necessary to understand the distinction between branded drugs and generics. The entire issue of cheaper generics is based on an assurance of quality of the drug. It is based on the premise of measurable and enforceable assurance about the quality of the drug through bio equivalence tests and other globally mandated parameters, unfortunately not being implemented in India.

In India in the absence of an international standard drug regulatory mechanism like the USFDA, the Indian doctors have to rely on the reputation of well-known companies like Cipla or Sun for quality assurance. Hundreds of such pharma companies who have demonstrated their commitment to quality of drugs over time have become trusted names in the eyes of doctors, chemists, and patients.

Reasons for the low prices of generic drugs

Due to high manufacturing, marketing and branding costs incurred in branded medicines are expensive. Branded drugs are bound to cost higher to recover these higher costs. The generic drugs differ from their branded counterparts with respect to price. The lower prices of generic drugs without brand names are due to their manufacturers don't need to incur huge expenditure towards marketing and sales promotion. As there is no need of high marketing costs generic drugs are cheaper promising the same result as the branded ones. Generic drugs are chemically identical to their branded counterparts, but sold at lower prices.

The significance of brand name for drugs

In India people are influenced by the "brand name" of a product, be it clothes, cosmetics, accessories, grocery, consumer durables or medicines. In the Indian pharma market, the brand names are more popular. Certain brand names of medicines have a powerful impact on people's minds to the extent that both the medicine and the brand names have become synonymous. In the over-the-counter (OTC) segment of drugs, the majority of people are aware of the brand names, rather than their chemical or generic names.

India, a major exporter of generic drugs, lists over 90,000 brand names for drugs. Though India is largely a generic drugs market, companies differentiate their products through brand names that command higher prices and market share. The term 'branded generic' is an Indian creation. 'Branded generic' is an oxymoron and represents Indian pharma industry's effort to distinguish branded generics from company A with the branded generics of another company B.

Speaking for the Indian Drug Manufacturers' Association, Daara Patel said that as drug makers, they would make generic or branded medicine, as required. However, he said, "brands have been developed over the years and doctors and patients develop confidence in them." Doctors prescribe them based on experience and the patient's feedback.

Why Indian doctors are reluctant to prescribe generic drugs

While prescribing a generic medicine the doctors are supposed to write the name of the salt and not the brand name of the drug under which the salt is manufactured. The Head of the ethics committee of the Delhi Medical Council, Dr. Krishan Kumar Aggarwal, a senior cardiologist in New Delhi told the BMJ: "Doctors in India are already prescribing generic drugs but through their brand names". The doctors' question is that if the authorities want the doctors to prescribe drugs through chemical names only, then why they do allow so many brand names. They further question why there is such wide price variation.

Doctors try to explain that the branded generics are also generics with a brand name, plus the quality assurance from well-known companies like Cipla, Sun or Dr. Reddy's. Over a period of time, the Doctors have come to trust these companies and their brands. Indian pharma industry with its field force of nearly one million medical representatives has put a lot of efforts and hard work in building this trust in their companies and brands. It is not so easy and simply not possible for doctors to transfer this time-tested trust on branded drugs to generics, manufactured by strange and unknown companies. If a doctor prescribes a drug with only the pharmaceutical salt name, then the chemist may dispense it with another branded generic or with a generic drug of doubtful quality.

Dr. CM Gulati, Editor with drug journal MIMS, states that the move to implement the only generic prescribing policy is difficult to enforce as half the medicines marketed in India are made up of combination drugs with more than two ingredients. Efforts have been on since the 70's to get doctors to prescribe generic medicines. Such initiatives can have unintended fallout, say if a chemist gives the cheapest drug with questionable quality to a patient. The patient is a doctor's responsibility, but in such a context, the blame will lie with the chemist.

A key concern is that prescribing generic names could shift the "decision-making" from the doctor to the retail chemist who may not understand the scientific rationale or have the best interest of the patient in mind. "Now chemists will decide, maybe based on the margins they get. They are not competent to judge the efficacy, feedback etc, and this will not help patients as reduced prices may not be passed on to the patients," Patel cautioned. The doctors question that who will be held responsible if any generic medicine has an adverse effect on the patient. "Will the government or pharma companies take responsibility" asked Dr. Manjunath.

Dr. Kappoor told the BMJ "The first step should be to ensure quality standards, quality monitoring, and quality assurance. Unless doctors are convinced that there is uniform quality, independent of the source of the compound, I don't expect doctors in India will routinely write out prescriptions with the chemical names of drugs". We should not just produce generic drugs, but produce only quality generic drugs as it is a matter of people's lives. The government should have a proper monitoring mechanism in place for the production quality of these drugs" says Dr. Talwar.

A key red flag on prescribing generic drugs only policy is that it shifts decision-making on which generic drug should be prescribed, from the doctor to the chemist. Writing out all the key ingredients while prescribing even a simple medicine can be difficult, and if the chemist does not understand the prescription, it creates more problems. So the initiative that seeks to break the doctor-drug-company nexus could falter at the chemist, given the varying trade margins that companies would give.

Dr. Amit Sengupta of Jan Swasthya Abhiyan, feels that the generics only initiative "is not going anywhere". The structure of the domestic pharmaceutical industry is based on branded generics. Most of the doctors complain that there are not enough generic drug equivalents for branded medicines sold in the market. "There is a contradiction in asking doctors to prescribe generics only when the market is full of branded generics". No groundwork has been done to implement the initiative, he says, pointing to pharmacists who are not legally allowed to change or substitute medicines. And yet, pharmacists in chemist shops will now have to decide on which generic drug to be given to a patient. That is, if all chemist shops do indeed have qualified pharmacists.

Patients in developed countries get their medicines from a well-developed health care system and not the retail market. "India has a well-developed pharma industry and an underdeveloped health care system," he says. No effort to fix the retail market can work, as someone will emerge and rig the system, cautions Dr. Sengupta, making a strong case to strengthen the public health system.

Doctors say that "We don't oppose generic drugs. We will be happy if prices of drugs are cheaper in the country. Our concern is regarding the quality of drugs. Availability and disbursement factors are not yet properly addressed by the central and state governments".

The Best quality generic drugs are not available even in government hospitals, which constitute just 20% of medical care. How 80% of patients, who visit private hospitals, can get quality generic drugs is a big challenge for the government. Further, many states do not have their own drug-testing labs where the authenticity of generic drugs can be checked.

Different surveys have found that over 50% of generic drugs produced in India are of sub-standard. There are questions of bio-availability and other pharmacological issues in the production of these drugs. "At the same time, the price quoted on these generic drugs is sometimes exorbitant, as they are even more than that of branded ones," The IMA vice-president, said "We fear drug marketing will go uncontrolled, as it would be retailers who will call the shots"

All generics are not equal

Following the Centre's advisory to physicians to prescribe drugs with generic names only; doctors across the country are worried that any change in a drug, especially for patients with chronic illnesses and critical care may risk patients not getting the full benefit of a particular drug. There can be complications and some of the ailments and diseases can go out of control. "There are serious concerns, and several organizations, including the Indian Epilepsy Association, the Indian Academy of Neurology and the Movement Disorder Society of India will soon write to the Centre raising the concerns," said Dr. G.T. Subhas, president of the Indian Epilepsy Association.

According to Dr. Puneet Dhamija, department of pharmacology AIIMS Rishikesh, all generics are simply not equal. When it comes to NDDS drugs (Novel Drug Delivery System) these drugs are more complex than those used in other fields of medicine. For example, complicated diabetes drugs like Metformin-sustained release (SR) and Gliclazide modified release (MR) have unique attributes, which are completely distinct and different from immediate release formulations. There are millions of patients suffering with asthma who depend on metered-dose inhalers of Cipla or GlaxoSmithKline to manage their chronic asthmatic condition. A poorly qualified and ill-trained retail chemist may not be able to make the distinction to dispense these highly differentiated inhalers through a generic prescription. Branded generics ensure that patients get the correct medicines. Critical aspects such as NDDS in branded generics must be considered while mandating generics-only prescriptions policy.

Dr. Ch Mohan, a neurologist said "in cases like brain haemorrhages or problems related to the other vital organs, we don't take risks by prescribing generic medicines. In fact, in most of the cases, the medicines for such illnesses won't be available, and we don't want to risk the patient's life". In some cases, the patients themselves do not show interest in using substandard generic medicines and insist the doctors to prescribe good quality branded drugs.

What the doctors say about the quality of generic drugs

Ensuring equitable access to essential medical products and vaccines is an important function of a well performing health care system. It should assure quality, safety, and efficacy, scientifically sound and cost-effective use of drugs.

A senior doctor of neurology from the AIMS, New Delhi states that "while the concept of reducing the cost is welcome, stringent quality checks of generic drugs are missing in India. Dr. Vinay Kappoor, professor and gastrointestinal surgeon at the Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow states that "Perceptions of quality of drugs are not unfounded and cannot just be wished away,"

In India, the bio availability of a generic drug molecule is not assured by quality control or clinical trials. Dr. Manjunath, Director of the State-run Sri Jayadeva Institute of Cardiovascular Sciences, points out that "the very fact that the same company manufacturing a branded drug also manufactures a generic drug means that there is a shift in quality, one should not compromise on quality of drugs, particularly in the critical care sector, including cardiac emergencies"

"Anywhere else in the world, generics will undergo scrutiny and a particular drug is manufactured by a single company only. Here, tens of companies manufacture the same drug and the final call will be taken by the chemist, who will use the opportunity of selling the drug for which he gets the highest margin," said the doctor. "Say if it's a contraceptive or a cough syrup with more than one chemical, then it is confusing for the patient if we write only the name of the salt," says Dr. Kohli, adding that this would leave the field open for the pharmacist to dispense the drug of his choice.

"We are not the ones who fix the price, so why are we being blamed? The drug regulator should put a price cap on all drugs, just like they did with the coronary stents," says Dr. Kohli. Many doctors, such as Dr. Kohli insists that doctors will prescribe only drugs that are effective, and also offer cheaper alternatives for those who cannot afford. Branded generics, that dominate the drug market, are also important because of the issue of quality.

Dr. Gagandeep Singh, Secretary of the Indian Academy of Neurology said "Indian companies are manufacturing generic drugs will see the composition of a particular drug and manufactures them without any research and clinical trials." Terming Indian generic drugs as "illegal" going by the U.S. laws, it is a reverse process and there is no quality check," he said.

The confidence of government health care providers in the efficacy and quality of generic medicines is reflected in the following statements in a study "I am not sure from where it comes, and I am also not so sure about the content inside that generic tablet. We are also not sure of what is on the label and what is inside the tablet. In my opinion, generic should not be used". "Generic drugs (Government supplied medicine) will be very low in quality, and I am telling this from my own experience, if I ever happen to use my PHC paracetamol for my own children I myself put more amount of paracetamol to my child, the quality of medicine is low when compared to private medicines. I have also myself experienced the difference in effect".

In India, there are several false impressions about the quality of generic medicines, compared to the branded ones. Statements such as 'the more you pay, the better the quality' is often the basis on which generic medicines are weighed down. Are generic medicines, which are just the same compound as the branded medicine, but sold, at a fraction of the cost of branded medicine, really bad in quality? In an attempt to understand this, researchers from the Institute of Public Health (IPH), Bangalore, with the support of the Alliance for Health Policy and Systems Research of the World Health Organization, has assessed the quality of generic medicines and their branded equivalents in South India. This research is part of a larger study to understand how to improve equitable access to quality medicines for patients, generic medicines being an important way to do so. Using qualitative analysis, the researchers also developed a framework that explains the role of trust in improving access to quality medicines. "We knew from our previous research that improving the availability of generic medicines was not enough to increase its consumption. We also have to address the trust in medicines and in health services to improve access," explains Dr. Prashanth N Srinivas from IPH, who is the lead researcher of this study.

Most of the doctors at AIIMS are not sure about the quality of generic drugs. According to them "there are certain generic medicines that don't work like the branded ones, certain generic drugs are not prescribed, instead, branded ones are preferred." Some doctors say that they are as good and same as the branded ones while other doctors feel that they are not of good quality. Some others say that they are less effective. Most of the doctors are surer about the availability of the branded drugs rather than the generic ones as there is no advertising and marketing of generic drugs.

Doctors and health experts warn a series of health-related problems with the implementation of a generics-only rule. Since half the Indian healthcare market is made up of combination drugs and it would be impractical to ask doctors to prescribe a series of chemical names, said Dr. S. Srinivasan, member of the People's Health Movement, a New Delhi-based NGO. "Prescribing combination drugs with generic names is difficult". There could be a difference in quality between a generic drug and a branded one. As it is, quality control of drug manufacturing is very poor in our country.

Mandating generics only may turn out to be risky for patients," said Dr. K. Senthil, State president, Tamil Nadu Government Doctors Association. Dr. Senthil said there could be brand substitutions made by pharmacists if only generic names are given, which will not serve the purpose. "Instead, a law for manufacturers to use generic names could be brought in, and the doctors could write out both brand names and generics on their prescriptions" he added. "The idea is very good, but the government needs to ensure the availability of good quality generics," said Dr. Vijay Panikar a Mumbai-based diabetologist.

Responsibility of pharma industry

While the government wants to make cheaper non-branded drugs available to consumers, pharmaceutical industry executives said any law would have to stipulate that the drugs consumers get from pharmacists meet certain quality standards.

"Generics are fine, but there has to be a proper rigorous mechanism to enforce quality, like the U.S., and unless India evolves on that it will be disastrous," said Kiran Mazumdar Shaw, CMD of Biocon, a veteran of the pharma industry. "I think you cannot accept a situation where a company has a differentiated quality system for a branded product and its generic version. It is totally unacceptable. It has to be one and the same. We need to look into because it reflects very poorly on our quality system if that is the case. We need a regulatory system, a regulatory framework which ensures that every drug that is approved has the same level of safety, efficacy, and reliability. Then, you can say that the doctor must prescribe a generic drug and only the generic name and that any drug in the pharmacy would be able to comply with the quality expectations of such a quality drug, but we are not there yet."
On government's push for generic drugs, Shaw said, "Implementation is going to be very challenging because yet we are not ready. The second thing is I do not think doctors are convinced in their heart of hearts that generics are as good as the branded versions. In most countries that have this approach also have large procurement which is covered under a large national insurance kind of scheme, which India does not have.

"I think the quality aspect is very important for the government to address, to make sure that all companies in India are on the same quality footing," said Cipla's CEO Umang Vohra.

There is no national data comparing the quality of branded generics with unbranded ones. But some studies have shown that unbranded generic drugs, manufactured by the government units for the public health system, have quality issues. In 2012 a report presented by the country's federal auditor showed that 31 percent of drugs procured by the government for the Armed Forces Medical Stores were substandard. The results of the government's largest-ever national survey to test drug quality showed that roughly 10 percent of the drugs in the government supply chain were not of standard quality, compared to 3 percent of branded generic drugs available at pharmacies. In one of the study, 27 commonly-used medicines in the country were failed in the quality tests. These drugs were found defective on several counts, including false labelling and inadequate quantity of ingredients.

Substandard medicines ranges from drugs that don't work at all to those that don't work as expected by doctors. Substandard medicines are contributing to antimicrobial resistance - a major global health problem.

Indian drug makers manufacturing standards, including those of big companies, have been found to have fallen short of international standards in recent years. Indian pharma industry experts feel that it will take at least five years for Indian drug manufacturing standards to meet the standards of the United States; India's biggest drugs export market.

Experts say the priority of the government should be to bring a legal framework to ensure "quality" in generic drug testing. Less than 1% of generic drugs sold in India undergo quality tests. Ensuring quality of generic drugs is a major problem in the absence of stringent quality regulations. and the shortage of drug inspectors and infrastructure and lab facilities to check drug quality. The number of drug inspectors, approximately 1,500 now must be increased. "Generic drugs should work therapeutically. The government should ensure uniform quality, and then only the doctors can prescribe them with confidence".

Though the use of generic medicines is steadily increasing worldwide, negative perceptions about their quality remain. Negative perceptions towards generic medicines affect their usage and raise questions of confidence in medicines as well as in health care providers who are prescribing and dispensing these medicines. If perceptions that are unfounded in empirical evidence are allowed to persist, they can negatively influence the utilization of health services. Patient perception of quality of drugs is one of the important drivers contributing to patients choosing expensive health care in the private sector over comparably cheaper health care in government health centers. Policies and programs that seek to improve generic medicine availability need to invest in building trust in medicine quality. There is a certain section of the population who feels that since generic drugs are comparatively cheaper, they are of inferior quality. An ongoing concerted effort of vested interests is systematically trying to malign the minds of many, projecting that those cheaper drugs are inferior in quality. Many medical practitioners are also not excluded from nurturing this possible spoon-fed and make-believe perception, including a section of the media.

This reminds the famous quote of Joseph Goebbels the German politician and Minister of Propaganda of Nazi Germany till 1945: "If you tell a lie big enough and keep repeating it, people will eventually come to believe it."

More than 73% of the doctors were against the decision of prescribing generic drugs only

The Centre's move towards forming a legal framework to make doctors prescribe generic drugs only and the subsequent notice by the Medical Council of India enforcing the same has failed to find many takers in the medical field.

Curofy, an online community of verified doctors, conducted an opinion poll on generic drugs. Out of 5,673 doctors who participated, 73% were against the decision. Across tier 1, 2 and 3 cities, the doctors were united in their disagreement with the decision.

"It's surprising to see that a large percentage of healthcare professionals don't support one of the landmark decisions that could affect patient health adversely," Interestingly, more super specialists were against this decision than general physicians. Within super specialists, Gynaecologists (89%), pulmonologists (93%) and intensivist (internal medicine) (89%) disapproved of this ruling than other specialties.

The doctors were concerned about the quality of drugs dispensed. One doctor stated, "Can the government guarantee the quality of drugs available in the market?"

Another doctor said, "Who will take responsibility for quality of drugs? Will patients not come to the doctor, but go to the pharmacist if the drugs are ineffective?

Medical Council of India guidelines for doctors

Medical Council of India (MCI), which registers doctors and ensures proper standards of medical practice in India, has issued necessary notifications regarding the prescription of generic drugs only policy. MCI has notified an amendment in Clause 1.5 of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, which stipulates that "Every physician should prescribe drugs with generic names legibly and preferably in capital letters, and he/she shall ensure that there are a rational prescription and use of drugs".

Medical Council of India, through Circulars dated 21.04.2017, 22.11.2012 and 18.01.2013, has reiterated that all physicians should prescribe drugs with generic names. Director, CGHS has through its Office Memorandum dated 08.09.2017, issued instructions to all CGHS Wellness Centers to ensure that all prescriptions are to be only by generic name wherever generic drugs are available. The MCI or the appropriate State Medical Councils have been empowered to take disciplinary action against a doctor for violation of the provisions of the aforesaid Regulations.

"The MCI directive does not prohibit doctors from writing brand names. It clearly urges medical professionals to write the salt name or the chemical compound along with any branded drug that they would want to prescribe to ward off any confusion on the part of the patient's lack of knowledge".

"Statutory Direction" to State Governments

The Central Government from time to time had issued circulars and instructions to government hospitals and Central

Government Health Scheme (CGHS) dispensaries to "prescribe generic medicines" to the "maximum extent possible". In December 2012, the UPA government had issued a "statutory direction" to state governments under relevant sections of the Drugs and Cosmetics Act, 1940 to "grant/renew" licenses to manufacture for "sale or for distribution of drugs in proper/generic names only". This direction was intended to build a mechanism for wider use of generic drugs.

IMA interpretation, the right of choice

The Indian Medical Association (IMA), while welcoming the push for generic drugs, insists that it is "discretionary and non-mandatory". Strict implementation of the existing laws should suffice in this regard,"

According to IMA interpretation, the MCI circular doesn't stop doctors from writing a brand name in a prescription; it is "discretionary and non-mandatory". Following the MCI circular, IMA national president Dr. K.K. Aggrawal wrote to MCI chief Dr. Jayshreeben Mehta saying: "The MCI rule said 'should prescribe drugs with generic names'. It does not say 'only' with generic names. It does not prohibit a doctor from writing the name of the company or the brand. Prescribing drugs with generic names only mean writing the chemical name of the drug."

Dr. Aggarwal further said: "Only the mandatory portion of the clause (prescription shall have rationality of treatment and the drugs prescribed) can be actionable. The non-mandatory initial part of the clause (should prescribe drugs with generic names) cannot lead to action by MCI. Also, 'every physician' in the clause means only those doctors who are registered under the Indian Medical Register (IMR)."

IMA senior vice-president Dr. Ajay Kumar said: "Medical bodies are not resisting the MCI rules. We're happy to prescribe generic drugs. However, the MCI rules do not ask doctors to mandatorily write only generic drugs. It says doctors 'should' write drugs with 'generic names'. It further said that doctors 'should' prescribe 'rationally.' What we want is that before the government makes generic drugs mandatory, it must arrange production and availability of quality generic drugs and stop production of branded drugs (except patented drugs) completely."

To clear this confusion, IMA and Federation of Medical Associations of India (FOMA) have decided to meet Prime Minister Narendra Modi, Union health minister and MCI president Mehta to apprise them of the medical fraternity's view on the issue. FOMA wants the government to first strengthen quality control mechanism to ensure supply of quality drugs before making generic drugs compulsory.

Dr. Aggarwal told The Hindu that "the concern of the medical profession regarding spurious and substandard drugs is yet to be addressed and more such drugs might get into the market under the guise of generic drugs" The government has only around 1,800 drug inspectors for the entire country, which is grossly inadequate. "The government itself admits that less than 0.01% of the drugs produced in the country are tested for quality. It will not be fair on the part of the government to expect doctors to prescribe substandard drugs,"

MCI's circular merely calls on doctors to prescribe drugs with generic names and mention the name of the salt, but they are not prohibited from writing the company name or the brand to provide the best quality, said IMA, an umbrella body representing doctors. "The medical practitioner ultimately has the right to choose the drug and the brand. But along the brand, they must mention the generic name. They must also justify why Rs 90 drugs have been prescribed when Rs 1 drug is also available in the market," said Dr. K.K Aggarwal, President, IMA.

Dr. S. Srinivasan of All India Drug Action Network states that "I do not think it is legal, because it is just part of the code of the conduct. The September 2016 amendment of the Medical Council of India is listed under the duties and the responsibilities of doctors and it does not say that if I do not do this, if I do not prescribe a generic, what will happen to me, it does not say that. There is no question of punishment in this. And if you are going to punish, how are you going to punish? There are so many, about seven lakh doctors in this country. So, I think it has to be something much more practical. The other thing is as long as there are brands and brand named drugs in this country you cannot really implement this requirement. First of all, make all the drugs of good quality and then remove brands as in many of the better-regulated countries."

Doctors insist that they need to retain the right to prescribe branded generics, and writing branded drugs were not "illegal". "Writing a complete and legible prescription does not forbid the medical practitioner from suggesting one or two best quality manufacturers of the drug to ensure quality," says Dr. Prem "If a doctor is writing the brand name, then the generic exposition should also be included. The prescription should include the generic name of medicine, route of administration, dose and frequency, time of administration and for the duration it has to be taken". Doctors should also avoid irrational combinations of drugs, and medicines should be written in capital letters, clear language, legible and should be dated, timed with the doctor's name and his signature, he added.

Without a proper planning and implementation strategies for long-term, the generics-only dictate has caused nothing more than pandemonium. The IMA cleverly interpreted the MCI order on generics as voluntary, and issued detailed guidelines to doctors that imply that "Nobody can stop doctors from choosing a company or brand for quality assurance."

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) is a social welfare scheme designed to bridge the gap between supply and demand of quality generic drugs. It is dedicated to provide quality medicines at an affordable price to every citizen of the country, irrespective of caste, creed and economic status. The intention is to provide health security to all our countrymen. Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) was launched by the Department of Pharmaceuticals. Bureau of Pharma PSU's of India (BPPI) is the nodal agency of implementation for PMBJP. The first "Jan Aushadhi Medical Store" was inaugurated on 25 November 2008 at Amritsar in Punjab. As of 05.03.2018, a total of 3214 PMBJP stores has been opened in 33 States/Union Territories of the Country.

PMBJP stores have been established to provide generic drugs at lesser prices, but are equivalent in terms of quality and efficacy as expensive branded drugs. Now this scheme covers more than 700 medicines and 154 surgical and consumables

covering all major therapeutic groups such as Analgesics, Antipyretics, Anti-allergies, Anti-infective, Anti-diabetic, Cardiovascular, Anti-cancer, and Gastro-Intestinal medicines.

Role of retail chemist in health care

Retail chemist is the meeting point for a patient with the prescription from a doctor and where the exchange process of money for products is completed. Retail chemist is the ultimate destination in the supply chain management in pharma marketing. Retail chemists have thrived because it is a high-margin profit business. Whether branded-generics or unbranded generics, a chemist will stock and sell drugs only if they are profitable.

Doctors have said that prescribing drugs without their brand names leaves the decision of which drug to sell at the hands of a pharmacist. The doctors expressed their concern about the educational qualification of chemists who will now be the decision-maker. Doctors warn that the new law would put too much power in the hands of the chemists potentially jeopardizing patient care. If the same drug with same composition is available in the market at varying prices, how can a consumer decide which one is better to buy? Does the choice get vested with the retail chemist? Yes, in this case the power shifts to the retail pharmacists. Then how can we know that the pharmacist is not selling any locally-manufactured, substandard drug to achieve his highest retail margin?

A large number of patients in the country are illiterate and even many literate patients are not well-versed with medical terms and drug composition. A patient with a prescription of the generic medicine is still depending on a pharmacist to make the most suitable drug choice. And by all accounts, a pharmacist is likely to be even less sensitive to a patient's medical and financial condition than the doctor. Dr. Panikar said "if I write a generic, the chemist will decide which drug to be given, and he will obviously give the one in which he has the biggest margin, without caring about quality,"

Long before the Medical Council of India (MCI) directive to write generics, these 14 lakh chemists have been selling unbranded generics at margins as high as 1000%. Expecting these 14 lakh chemists to suddenly transform and become charitable dispensers of low cost generics like a Jan Aushadhi store shows a complete lack of understanding how the system works. The retailers have repeatedly demonstrated their intolerance for any interference in their business by going on strikes and holding patients to ransom till their demands are met.

Any program related to health care will not be successful without active participation and cooperation of the retail chemist at grass root level. At this point of time the pharmacists at retailer counters are ill-equipped and not trained to dispense generic drugs accurately. The government must explore ways to educate, train and certify retail pharmacists as community pharmacists. Pharmacology and community medicine departments of medical colleges can be involved in this program.

CONCLUSION

Though the use of generic medicines is steadily increasing worldwide, negative perceptions about their quality still remains in India. Failure in understanding the behavior of doctors as consumers and lack of psychological aspects in marketing are the main reasons for the failure in promoting generic drugs, and for the reluctance of doctors in prescribing generic drugs. The generics-only dictate by the government is a non-starter. The basic thing, the law is not clear. The second and the most important part is that the doctors are not convinced in their heart of hearts that generics are as good as the branded versions in terms of quality. Generic only is a good idea on paper, but it is not implementable at the present point of time because it needs a lot of planning and prerequisites before implementing. Only a time-bound health policy involving all stakeholders and covering all aspects of healthcare can address these issues in a holistic manner. We need to invest in building trust in medicine quality. Critical nature of medicines calls for greater and in-depth debate on the issue.

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