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Review Article

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The Shift Towards Generic Medicine: A Pragmatic Approach by Indian Doctors

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Abstract

The pharmaceutical industry worldwide has witnessed a significant positive shift in recent years. In India, the discourse surrounding generic medicines has gained momentum, albeit with some challenges. The cost of research and development invested in the development of a drug makes it costly and unaffordable for most of the patients.

The Government of India has made various steps to introduce affordable drugs. However, it has not become very popular amongst patients. Various doubt and lack of confidence among doctors and patients regarding potency, efficacy, and quality is still a concern. There is a need for correct awareness to be spread amongst doctors and patients regarding generic medicine. The pharmaceutical industry also needs to be in the picture and promote positive awareness.

This article aims to shed light on the perspective of Indian doctors as they navigate the complexities of prescribing generic medicines without sufficient government support and limited patient awareness. This article also tries to shed light on the present scenario of how generic medicines are perceived by patients.

Keywords: Generic Medicine, Quality control, Doctors' Perspective, Jan Aushadhi, Medical awareness, Govt efforts, WHO, FDA

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1. Introduction

The pharmaceutical industry in India as well as worldwide has witnessed a significant positive shift in recent years, especially after the COVID-19 pandemic, and growing emphasis on the use of generic medicine. In India, the discourse surrounding generic medicines has gained momentum, albeit with some challenges. This article aims to shed light on the perspective of Indian doctors as they navigate the complexities of prescribing generic medicines without sufficient government support and limited patient awareness.

Understanding Generic Medicine

The WHO defines a generic product as "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". (1)

In the USA, the Food and Drug Administration (FDA) has stated that "A generic drug is identical—or bioequivalent-to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use". (2) The European Medicines Agency (EMA), the main regulatory body for pharmaceutical products in the EU, defines a generic medicinal product as a "product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. (Reg. 726/2004, Art 10, 2b)". (3) Finally, in India a generic drug is a medication created to be the same as an existing approved brand name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics. (4)

Generic medicine

Generic medicine refers to pharmaceutical products that contain the same active ingredients as their brand-name counterparts. These medicines are often marketed at a lower cost due to their generic nature, making them more affordable and accessible to a wider population.

Developing a new drug requires a large number of resources to carry out pre-clinical trials and tests to evaluate its benefits and short-term and long-term risks, which requires financial resources. To compensate for efforts put in by pharmaceutical companies, the company is given the right to recover financial benefits from the new drug developed for 20 years thereafter the original drug chemical can be prepared by other pharmaceutical companies. Generic drugs as per law should undergo strict quality control measures to ensure their safety, efficacy, and therapeutic equivalence to their branded counterparts.

The abbreviated new drug application (ANDA) process for the production of generic medicine does not require the manufacturer to carry out repeat testing of generics in animals which is often time-consuming, as their branded versions have already been tested and approved for the safety and effectiveness. They are formulated when the patent and other exclusivity rights of the innovator have expired. (4)

With a set background, Generic drug manufacturers do not have to spend extra money on drug discovery and preclinical and clinical trials.

2. The Indian Scenario

In India, where healthcare expenditure is a major concern, the provision of affordable medicines is extremely crucial. Recognizing this need, the Indian government introduced the concept of generic medicine through various initiatives, encouraging doctors to prescribe it. However, implementing this rule has proven challenging due to a lack of adequate support and insufficient patient awareness. (5)

In 2008, the Government of India, through the Department of Pharmaceuticals, started a new initiative "Jan Aushadhi" (a Hindi word translated as "Medicine for People"). This program envisaged making unbranded quality medicines available to poor people in the country at a reasonable and affordable price through retail outlets' setups with the help of the government. It has taken ownership of setting up Jan Aushadhi stores, which are pharmacies selling only generic name medicines to the extent possible, giving preference to pharmaceutical public sector undertakings too. (6)

Until March 15, 2018, 3200 Jan Aushadhi stores were operating in more than 33 states/union territories across India. (7) There are not enough Jan Aushadhi stores, possibly 3200 against more than 8 lakh retail pharmacies in existence, with many rural areas still underserved. (8)

The Medical Council of India, in an amendment to the code of conduct for doctors in October 2016, has recommended that every physician should prescribe drugs with generic names legible, and he or she shall ensure that there is a rational prescription that promotes the use of generic drugs. (8)

In the future, the Government of India may bring a legal framework under which doctors will have to prescribe generic medicines to patients. (9)

3. Doctors' Perspective

Indian doctors face several hurdles when it comes to prescribing generic medicines. One of the primary concerns is the quality of generic drugs. While stringent quality control measures should be in place, doctors must ensure that the generic medications they prescribe meet these standards for optimal patient care. A lack of transparency in the generic drug supply chain further impedes their ability to confidently recommend these medicines.

One of the main reasons for the lack of confidence in generic drugs among doctors (and even patients) has been the absence of stringent regulatory requirements for the quantity of the drug in its generic version and the permissible impurities in it. (10) The question raised quite often is "Whether the quality and performance of generic drugs is comparable to the brand drugs?" The proponents of generic drugs claim that they are equally effective as brand or innovator drugs. (11) After this claim, the Drugs Technical Advisory Board of India in May 2016 considered amending Rule 65 (11A) of the Drugs and Cosmetics Act, 1940, so that pharmacists can dispense generic name medicines and/or equivalent brands against prescriptions in brand names. However, skeptics have stated that the use of generic drugs may lead to prolongation of illness or even therapeutic failure as the bioavailability (BA) of a generic drug may not be as good as that of the prescribed brand. (8)

Brand names often carry an aura of trust, as patients are accustomed to associating specific brands with quality and efficacy. The widespread lack of awareness about the therapeutic equivalence of generic drugs among patients creates uncertainty and resistance toward their use.

Polypharmacy: Some brands provide a fixed drug combination of drugs for a specific illness. If separate generic medicines are prescribed it will account for 4-5 drugs which will challenge the complaints of the patient. For example, a fixed drug combination for the common cold contains an antipyretic, anti-histamine, alpha-blocker, and caffeine. Prescribing calcium supplements with Vitamin D, magnesium, and citric acid for better absorption and assimilation of calcium with a fixed dose preparation by a brand provides better compliance compared to prescribing individually.

Currently, when doctors write a prescription, they specify the type and dosage of the active pharmaceutical, but nothing about the inactive ingredients. Many medications come in dozens of different formulations, and the one that patients get depends on their insurance, their pharmacy, and the manufacturer that supplies the pharmacy. The information that comes with the medication usually lists inactive ingredients, but not the amounts of each one, and they may be difficult to decipher. For example, ingredients that contain gluten may not be listed as "gluten."

It is known that a few select excipients have the potential to alter the pharmacokinetic properties of an API, for example *via* physicochemical interactions, (12) or by modulating metabolic and transport enzymes. (13)

The substitution of a generic drug can sometimes cause other problems for the consumer. A doctor may prescribe a brand-name product and discuss the brand-name product with the consumer. If a pharmacist dispenses an equivalent generic product and the label does not also list the reference (brand-name product), the consumer may not know how the generic product relates to the drug the doctor prescribed. To prevent this confusion, most pharmacies now include the reference brand name on the label when a generic product is substituted.

Caution should be exercised when considering switching brands of drugs that entered the market before the 1938 Federal Food, Drug, and Cosmetic Act took effect (for example, digoxin, codeine, and phenobarbital). The few drugs in this category that are still prescribed are exempt from generic drug requirements. Switching among different versions of these drugs is unwise because no standards are available by which to compare them.

Other drugs for which generic substitution may not be appropriate include drugs that are said to have a narrow margin of safety because the toxic dose is too close to the effective dose for the drug to be used safely.

4. Overcoming Challenges

Health is the responsibility of the state. Providing adequate medical facilities for the people is an obligation undertaken by the government in the welfare state. Article 21 of the constitution of India imposes an obligation on the state to safeguard the right to the life of every person.

The responsibility of providing cost-effective and quality drugs to the patient is the sole responsibility of the government and not the doctors or pharmacists alone. Indian doctors can play a pivotal role in educating their patients about the benefits of generic medicines. By engaging in open and transparent conversations, on behalf of the state, doctors can effectively explain the cost-saving benefits, equivalent efficacy, and safety profiles of generics.

Furthermore, doctors can leverage digital platforms and social media to disseminate information and create awareness about generic medicines. Online resources, such as official government websites and trusted medical portals, can aid doctors in accessing reliable information to help them make informed decisions when prescribing generic drugs.

Collaboration and Government Support

In India looking at the affordability criteria, the Department of Pharmaceuticals, Government of India, established the campaign "Jan Aushadhi Campaign" in April 2008 with the main aim of providing high-quality generic medicines at lower prices when compared to branded ones in the market. The government opened Jan Aushadhi stores near public hospitals with the cooperation of the state government. (14)

Addressing the issue of generic medicine hinges on the collaboration between doctors and pharmaceutical manufacturers, doctors can ensure a steady supply of reliable generic medicines. Additionally, seeking support from government bodies to establish robust quality control mechanisms and increasing patient awareness can further facilitate the transition towards generic medicine.

Pharmacies and drug stores other than government-run hospitals and clinics hardly stock unbranded generic drugs. When a generic drug is prescribed, the pharmacist would likely dispense his favorite branded generic. Unless the prescribers are sure about the quality of generic drugs, compulsory prescribing in generics holds no breath. (15)

Central Drugs Standard Control Organisation is a licensing authority in India that has recently released guidelines for BA/BE studies. (16) It has given a checklist for the submission of documents before undertaking a BA/BE study but is not clear whether they will ensure the bioequivalence of each and every molecule. Confidence and habit of generic prescribing need to be inculcated into our medical fraternity by providing information and education, particularly in areas of bioequivalence, and regulatory aspects, and dispelling myths, fears, doubts, or false ideas about generic medicines. Only providing guidelines will not enhance the quality of drugs in the market and prescribing. On the other hand, ensuring quality with the strict regulatory mandate and providing updated information regarding generic drugs (as given by the United States Food and Drug Administration in its Orange Book) will eventually enhance the prescription of generic drugs.

Godman *et al*, have proposed a 4"E" (Education, Engineering, Economics, and Enforcement) methodology for promoting generic drug utilization and development in Europe, and the same can be replicated in India. The 4"E" include (i) "Education" - design programs to influence generic prescribing by disseminating educational materials; (ii) "Engineering" - Focus on organizational interventions to evolve agreements on the price and volume of existing drugs about disease management programs; (iii) "Economics": Increase generic drug utilization through the use of positive and negative incentives for physicians and patients (iv) "Enforcement"- initiate regulatory or law enforcement methods which may include mandatory generic substitution laws to which pharmacists must adhere. (17)

5. Conclusion

Health is a state matter and the government needs to bring in methods to boost confidence in the doctors as well as patients concerning generic medicine.

While the prescription of generic medicines in India is hindered by a lack of government support and limited patient awareness, Indian doctors are proactive in advocating for their merits. By actively engaging with patients, and educating them about the equivalency and cost-effectiveness of generic drugs, doctors can play a pivotal role in bringing about a positive shift towards embracing generic medicine.

To fully unlock the potential of generic medicines, collaboration between all stakeholders, including the

government, is essential. With the right support and awareness, generic medicines have the potential to revolutionize healthcare accessibility in India, bridging gaps and creating a more equitable healthcare system for all.

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Conflict of Interest

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