Generic drug usage: Massive Adoption, Multiple Perspectives, Challenges and Outcomes

Dr. Mousumi Bhattacharjee James,
Assistant Professor, Applied Chemistry
Department of Humanities and Applied Sciences.
New Horizon Institute of Technology and Management, Thane, Maharashtra., India
mbjames1@gmail.com

Abstract: **Today the world is constantly witnessing quite a stir associated with the usage of generic drugs. Diverse, comprehensive and complex, viewpoints and perspectives are being exchanged by pharmacists and business giants on various aspects to denote the significance of generic drug usage across the globe. Exhaustive study and exchange of view-points are being conducted across the globe so that not a single perspective is left untouched. A generic drug is a pharmaceutical drug that has the same chemical substance as the drug that was originally developed, patented and innovated. Generic drugs are allowed for sale after the expiry of the patent of the original drugs. The most pertinent perspective regarding the usage of generic drugs is the quality view point, as any compromise on this aspect is directly linked with a fatal and cataclysmic outcome involving human life. Though cost often correlates to quality, but the FDA regulates this factor and a generic while far less costly has the same ingredient and quality. Drug distribution often plays a very critical role in the usage of pharmaceutical preparations. The disparity is majorly seen in under developed countries. In developed countries where the majority of the population is literate and covered under healthcare insurance schemes the savings by usage of generic drugs isn't a concern of the end user. Awareness of mandatory norms etc facilitates their choices. But in developing economies, with unavailability of medical insurance, where a wide majority of the population is illiterate, the dependence is largely on the dispensers. While Prime Minister Narendra Modi has made the prescription of generic drugs mandatory and the Medical Council of India (MCI) has already declared it an ethics code for doctors but the implementation of the same is still under process. In the management of diseases, the role of cost of therapy is a major concern. Massive shifting to generic drugs could prove to be a blessing in the management of chronic diseases. But then there is more to just one side of the coin. The issue is more complex than it seems to be. Certain facts have been reiterated for general awareness. Though the usage of generic drugs is proven to be a boon for the consumer with significantly lower cost of therapy, but multiple factors need to be under control till it is finally mass implemented worldwide. This might take a slightly longer time frame than anticipated but once done will indeed be a blessing for the ailing humanity.**

Keywords: Generic, Pharmaceutical, Patients, Consumers, bioequivalence, brand-name, dosage, FDA, WHO, Chronic diseases.

I. INTRODUCTION:

Today the world is constantly witnessing quite a stir associated with the usage of generic drugs. Diverse, comprehensive and complex, viewpoints and perspectives are being exchanged by pharmacists and business giants on various aspects to denote the significance of generic drug usage across the globe. As, this is a context of grave importance and directly relates to the life of mankind hence this subject needs to be brainstormed by experts in related fields constantly and from various frames of significance. Exhaustive study and exchange of view-points are being conducted across the globe so that not a single perspective is left untouched. With the development of newer drugs, delivery systems and older drugs going off patent, the pharmaceutical sector has also entered a highly competitive mode to evolve itself to keep pace with their counterparts in coming up with beneficial prerogatives to serve mankind. Widespread usage of generic drugs seems to be the most lucrative option which could bring down the expenditure incurred on healthcare for the consumers across the globe. This contention or vital subject might appear to be a simple thing with an uncomplicated solution, but this actually, has not even two sides of the coin but multiple aspects to be explored before concluding. Hence worldwide the usage of generic drugs on a massive scale is being discussed and debated on an extensive scale. In such a scenario there are multiple aspects to be explored before arriving at the final word. With the increase of lifestyle diseases like Diabetes, hypertension, Cardiovascular diseases, obesity etc. and occupational lifestyle diseases[1] which include those caused by the factors present in the vicinity like heat, sound, dust, fumes, smoke, cold, and other pollutants which are inevitably responsible for allergy, respiratory, hearing problems, and heat or cold shock. All these and many more factors have imperiously driven major part of the population to be under some kind of therapy in routine almost alongside their daily diet. Then with the

worsening environmental status which again is a global concern, diseases pertaining to this factor, mutation of micro-organisms, disease outbreaks are so commonly encountered that knowledge about essential and basic pharmacological awareness now seem to be a mandate for the common man. Improvement of mortality rates due to access of advanced medical facilities for the common man has immensely increased the life expectancy. This definitely means that each individual must include medical expenses in their regular budget. Specifically, in developing countries like India where the benefits of health insurance have not impacted the massive part of the population, a general know how about the usage of generic drugs needs to be explored. This paper has been written in the interest of intellectuals with non-pharmacy background for their acquaintance about the usage of medication. The aspects explored and reviewed would be quality, bioequivalence, packaging, pricing, mandatory laws and regulations, distribution and dispensing,

II.GENERIC DRUGS KNOW HOW:

A generic drug is a pharmaceutical drug that has the same chemical substance as the drug that was originally developed, patented and innovated. Generic drugs are allowed for sale after the expiry of the patent of the original drugs. Because the active chemical substance is the same, the medical profile of generics is believed to be equivalent in performance. As per Wikipedia, the generic drug has the same Active Pharmaceutical Ingredient (API) as the original, but it may differ in characteristics such as manufacturing process, formulation, excipients, color, taste, and packaging. As referred in a study[2] the term "generic drug" or "generic medicine" could have multiple definitions in different markets, however the term is commonly understood, as defined by the World Health Organization (WHO), to mean a pharmaceutical product which:

- Is usually intended to be interchangeable with an innovator product,
- Is manufactured without a license from the innovator company, and
- Is marketed after the expiry date of the patent or other exclusive rights[3]

There are differing legal requirements in different jurisdictions that define the specifics of what a generic medicine is. However, one of the main principles underpinning the safe and effective use of generic medicines is the concept of bioequivalence. As per USFDA a generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate bioequivalence, which means that a generic medicine works in the same way and provides the same clinical benefit as its brand-name version. In other words, you can take a generic medicine as an equal substitute for its brand-name counterpart. Food and Drug Administration's review process ensures that generic medications perform the same way in the human body and have the same intended use as the name brand medication. Health care professionals and consumers can be assured that FDA-approved generic drug products have met the same rigid standards as the innovator drug. All generic drugs approved by FDA have the same high quality, strength, purity, and stability as brand-name drugs. In addition, FDA inspects facilities to make certain the generic manufacturing, packaging, and testing sites pass the same quality standards as those of brand-name drugs [4].

Generic Drugs-The Pricing Aspect: A report of WHO[5] while exploring the aspects describe the prices, availability and affordability of some medicines for chronic diseases for patients with specific diseases in a number of countries. They went on to state that in low- and middle-income countries, majority of the population have limitedaccess to medicines, either because of poor availability or because patients must pay for theirprescriptions and are not able to do so. So considering vital factor we must agree that cost of therapy is a major determinant in one's treatment as it decides the complete medical management of the patient in long term. Hence usage of generic medicines is being recommended in low income group countries. As per a review article[6] brand-name drugs have been shown to be priced 20 percent higher than generic drugs in the Netherlands, 30 percent higher in Germany, 50 percent higher in Canada, 50–90 percent higher in the US, and 80 percent higher in the UK[7] whereas the cost to the patient in India based on a study of selective medicines was 31-41% higher for branded drugs as compared to their generic counterparts. This study also revealed an interesting fact that the profit margins for generic drugs offered to retailer was in the range of 201-1016%, which was an enormous difference and could make the retailers promote generics for their personal benefits. A fundamental reason for this price discrepancy between generic and branded drugs is the enormous costs incurred during their research and development. Obviously, the organizations investing significant funds into developing novel drugs charge high prices for their products in order to recover these expenses. It is also likely that companies introducing novel drugs incur large marketing costs, due to the lack of knowledge among physicians regarding the ability of a newly introduced drug to treat a given disease. This further escalates the initial costs of these firms. Apart from just development cost there is an estimated cost of drugs which are ultimately left unapproved. A recent report [8] specifies this fact that the companies had a number of drugs in clinical development that have not been approved and that an overall clinical approval success rate was for these companies was just 23%. This report went on to specify that research and development costs associated with the purported failures are also likely underestimated since they could have incurred costs outside of the periods examined. The book [9] summarizes key components of R&D Costs specifying four main variables determining the capitalized cost of a new drug estimate out-of-pocket costs, success rates, development times and the cost of capital. The book states that, given the long timescales required to develop a new drug and the associated risks, we need to allow for both failures and the cost of capital to compute the total cost of a new successful drug, i.e. not just the out-of-pocket costs. Further the book states that capitalized cost is the standard accounting treatment for long-term investments. This recognizes the fact that investors require a

return on research that reflects alternative potential uses of their investment. Further clinical trials which are the lifeline of introduction of a new drug, cost the pharmaceutical companies quite an enormous fortune. A research paper on this burning issue [10] cites that Clinical trials are a crucial part of the drug development process. Clinical trials conducted to demonstrate safety and efficacy for approval from regulatory bodies cost a huge sum of money. The paper enumerates that in 2003, the estimated cost of bringing a drug to market was US$802 million which has escalated to $2.6 billion in 2016. This fact has been escalating and the cost discourages pharmaceutical companies to go for new drug development and consequently limits patients' access to novel treatments. Companies are looking for possible ways to cut down the cost of clinical trials.

The Quality View Point: The most pertinent perspective regarding the usage of generic drugs is the quality view point, as any compromise on this aspect is directly linked with a fatal and cataclysmic outcome involving human life. The majority of the population is concerned because generic drugs are often substantially cheaper than the brand-name versions. This aggravates their concern whether the quality and effectiveness of the drug has actually been compromised to make the less expensive products. This isn't the fact as The FDA (U.S. Food and Drug Administration) requires that generic drugs be as safe and effective as brand-name drugs. Bioequivalence is the property of any API (Active Pharmaceutical Ingredient) which directly relates to the quality viewpoint. Studies conducted world-wide have substantiated both the notions that is for and against the interchangeability of generic drugs. A study on cardiovascular drugs [11] suggests that evidence does not support the notion that brand-name drugs used in cardiovascular disease are superior to generic drugs, a substantial number of editorials counsel against the interchangeability of generic drugs. In another research paper[12] concludes that a meaningful proportion of physicians expressed negative perceptions about generic medications, representing a potential barrier to generic use. They suggested that Payers and policymakers trying to encourage generic use may consider educational campaigns targeting older physicians. A fact that insurers and policymakers encourage the use of generic drugs to reduce costs, but generics still remain underused was brought forth by a paper [13]. A view point discussed earlier in this paper[14] highlights that though the quality of *branded-generic*s is same as for their *branded* version, there are still other implications. The study highlights the need to modify the drug price policy, regulate the mark-ups in generic supply chain, conduct and widely publicize the quality testing of generics for awareness of all stakeholders. In April 2017, the Indian Prime Minister Narendra Modi announced that the Government would establish a legal framework mandating doctors to prescribe medicines by their International Nonproprietary Name (INN) only (PM's Speech in Surat while inaugurating the multi-specialty hospital and research center of Samast Patidar Arogya Trust, April 17, 2017). To ensure quality of generic drugs approved by the State FDAs, the Union Ministry of Health (MoH) issued a notification in April 2017 10 (GSR 327(E) dated April 3, 2017)requiring bio-equivalence (BE) studies to be conducted for all drugs (new or otherwise) of the biopharmaceutical classification system.

Pharmaceutical Packaging- A Vital Component: Pharmaceutical packaging or drug packaging is certainly a very important aspect as packaging processes for pharmaceutical preparations are a vital part ensuring dispensing till it reaches the end user . It involves all of the operations from production through drug distribution channels to the end consumer. packaging is highly regulated but with some variation in the details, depending on the country of origin or the region. Several common factors can include: assurance of patient safety, assurance of the efficacy of the drug through the intended shelf life, uniformity of the drug through different production lots, thorough documentation of all materials and processes, control of possible migration of packaging components into the drug, control of degradation of the drug by oxygen, moisture, heat, etc., prevention of microbial contamination, sterility, etc. Packaging is often involved in dispensing, dosing, and use of the pharmaceutical product. Communication of proper use and cautionary labels are also regulated. Packaging is an integral part of pharmaceutical product [15] Though there are recognized process validations, theories, and tools and how they go above manufacturing and packaging of all dosage forms, but still certain conclusions are unaffected. End users often go by the packaging which relates to their brand loyalty and to a large extent affects their psyche.

Drug Distribution and Dispensing Scheme: Drug distribution often plays a very critical role in the usage of pharmaceutical preparations. The disparity is majorly seen in under developed countries. In developed countries where the majority of the population is literate and covered under healthcare insurance schemes the savings by usage of generic drugs isn't a concern of the end user. Awareness of mandatory norms etc facilitates their choices. But in developing economies, with unavailability of medical insurance, where a wide majority of the population is illiterate, the dependence is largely on the dispensers. The dispensers can be pharmacists at a retail outlet or even one in a PHC (Primary healthcare centre). Dispensing malpractices are quite prevalent and there have been multitudes of cases as such specifically in the sub-urban or village areas, where dispensing errors have been committed and the patient had been given an altogether different drug with the notion of substituting the branded drug for its generic version. While Prime Minister Narendra Modi has made the prescription of generic drugs mandatory and the Medical Council of India (MCI) has already declared it an ethics code for doctors but the implementation of the same is still under process. There is more to it than just one side of the story. On one side the lower-cost generic drugs increase the chances that patients takes essential medications prescribed by their doctors and to improve patients' health outcomes. But this certainly has positive outcomes if the prescription has the generic names mentioned and are not left to the choices of the retailers whose discretion is often governed by

their profit margins. In developing or under developed countries another phenomenon is often reported, where the patient opts for a part of the prescription to cut the cost. In such a case he goes by the advice of the retailer to be selective regarding the most essential drugs in his prescription. There are often chances of error as the doctor is unaware, that a dispensing error has been done. Erroneous dispensing can surely result in serious or even fatal outcomes. Hence the inhibitions of medical practitioners specially in case of medications in life threatening conditions, for the use of generics can be presumed.

The Brand Loyalty factor: It has been observed that patients undergoing chronic therapy and under medication for many year often develop an affinity towards certain brands which have cured their distress and hence are inclined to continue with the same. In case of a generic alternative the appearance of the drug may change. Although variations in appearance should not affect the effectiveness or safety of the drug, but the psyche of the patient is involved and he tends to believe otherwise. The same often happens with certain medical practitioners who have developed a liking or loyalty for certain drugs as a result of their excellent clinical outcomes. They often prefer to use their favorite brands and hence acceptance of generics tend to be difficult. As put forth by many publications, one such quoted[16.] Brand loyalty is a powerful tool in the development of pharmaceutical brands. Physicians play major role in the selection of drugs to consume and can also be considered as the consumer.

CONCLUSION:

Though the usage of generic drugs has caused quite a stir and implies direct benefits to the patients and considered as a boon for specifically developing countries where medical benefits are still not up to the mark. In the management of diseases, the role of cost of therapy is a major concern. Massive shifting to generic drugs could prove to be a blessing in the management of chronic diseases. But then there is more to just one side of the coin. The issue is more complex than it seems to be. Certain facts have been reiterated for general awareness, for instance Generic drugs are replicas of patented drugs and can be marketed at low cost after patent expiration of the brand- name preparations. As per review paper by same author [17] the difference between Generic and Brand Name Medications must be clear to the end user or the patient. They must be aware of the difference that every medication produced today has a generic name, which is almost always the name of the drug's active compound. Although the development of generics are under the regulation of strict mandatory guidelines, a number of issues and concerns often cause a dilemma which undermines the confidence of physicians and patients for mass usage of the same. The mandatory laws for enforcements and implementations play a major role. Brand loyalty, consumers and physician's perceptions, govern a major scenario. Substitution in emergency medicine a point of debate. Mindset of physicians as they have been using a certain brand for years especially older physicians. Dispensing difficulty is obvious in underdeveloped countries where brands are often identified by colours and packaging. Substitution of branded drugs by their generic counterparts often poses difficulty in administering the medicine in old age patients without caretakers. We are all moving towards a optimistic era when negative factors will be under control and the positives potentiated. Though the usage of generic drugs is proven to be a boon for the consumer with significantly lower cost of therapy, but multiple factors need to be under control till it is finally mass implemented worldwide. This might take a slightly longer time frame than anticipated but once done will indeed be a blessing for the ailing humanity.

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