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### **Irony- India is a hub for Generic Medicines while Indian Doctors are yet to adopt Indian generics - Qualitative Analysis**

**Rachna U. Trivedi\***

**Abstract :** The maintenance of drug quality is an essential component of medical care. Despite convincing scientific evidence that generic medicines are equivalent to branded medicines, there remains an issue of fear towards its quality in India. Doctors doubt the equal effectiveness of generic and brand name drugs. Reputation of the company, quality of drug and brand name, rapport with the doctors, launch meetings, incentives offers to the doctors, key opinion leaders, peers review, patients preference are factors influencing doctors' prescriptions,

India's status as a low cost manufacturing base has opened up the gates for counterfeiters. India being the world's largest supplier of generic drugs, has become an epicenter for counterfeit and fake drugs. A Series of scandals around the approval of generic drugs in the late 1980's shook public confidence in generic drugs. The prescribed purity of ingredients in India is 99% while standard elsewhere are 99.8%. (Bijon Mishra)

**Key words :** Generic drugs, Counterfeit, Malpractices, Good Manufacturing practices

#### **Introduction**

Generic drugs are medicines which are identical or are bioequivalent to brand name drugs in dosage form, safety, strength, route of administration, quality, performance, characteristics and intended use (29). Instead of clinical trials, bioequivalence studies are obligatory for generic drugs to be registered as a new product and launched onto the market.

Bioequivalence studies are mainly based on two pharmacokinetics parameters, AUC (area under the curve) from administration to last observed concentration and C<sub>max</sub> values must be within an acceptance range of 0.82-1.25 of those of the reference product (30,31).

The Indian Pharma industry is a highly knowledge based industry is 4th in terms of production volumes and over 55% exports are to highly regulated markets. (26). India is exporting quality generic medicines to 215 countries and is the "World Pharmacy". India's pharma sector is growing at a pace of 20-21%. (Agencies, 2017).

#### **Why Generics**

The economic benefits of generic drug use are however well known and undisputed. (2). There is no doubt that generic medicines offer cost savings, a big advantage in a country like India, where out of pocket expenditure accounts for the major sources (69%) of healthcare spending, and nearly 70% of it is spent on medicines. (32). For patients who suffer from diabetes or cardiovascular disease, and who may need certain medicines for months or even the rest of life. Generic drugs are generally seen as an important instrument for achieving better equality and access to drugs.

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(14) Generic substitution has been introduced in most countries in order to reduce costs and improve access to drugs(14). In order to reduce the growth in national healthcare spending, generic drugs are being increasingly used in most countries world wide. Treatments of many patients and in particular of those in developing countries, is now possible because of low cost generic drugs.(33,34,35). The high cost of some medicines in India has made the treatment of many common and uncommon diseases unaffordable to the poor and a strain on the budgets of even middle class citizens.(9.) Generic medicines can effectively treat many of today's illnesses and their use provides the opportunity to substantially reduce costs to healthcare budgets and patients,(36,37,38). Generic drugs saved the healthcare systems and consumers over \$192 billion worldwide in 2011 alone.(39). Generic pharmaceuticals are now seen as a critical component of the pharmacy marketplace by holding down rising healthcare costs which provide value to patients through access to a wide range of lower cost medicines.(Anonymous,2006). Generic prescribing result in lower pharmaceuticals cost and increased access to medicines.(40)

### Literature Review

Drug counterfeit has become a problem of immense magnitude world wide which has aroused a significant level of attention among researchers, managers and policy makers. The counterfeit drug industry is estimated to be worth \$200 billion a year(41) and has been defined as the "The crime of the 21st century"(ACG report 2003) present in almost every industry with Asia appearing to be the single largest producing region for counterfeit drugs. 75% of counterfeit drugs supplied world over have some origins in India, followed by 7% from Egypt and 6% from China responsible for 3000 deaths across worldwide per year. According to BASCAP- "Pharmaceutical industry is the most counterfeit industry in India". CDSCO conducted a nationwide survey in 2009, collecting 24136 samples from 1995-2008, out of which 1693 found counterfeited. The pharmaceutical security institute (PSI,2013) discovered 2,193 incidents of pharmaceutical crime during 2013.(26). A report by Rama Laxmi suggests that an estimated 12-25% of all drugs sold within India are thought to be counterfeit. India is not only one of the biggest producers of counterfeit drugs but it also has a huge market for spurious and counterfeit drugs(IMPACT). The developing countries are not merely the victims of the problem, but also serve as the source of fake drugs with India and China being the biggest culprits globally(42). One statistics by the European Commission described India as the source of 75% of fake drugs and according to one report; most of the fake drugs in Nigerian markets originated from India(43). Various studies have reported the widespread circulation of poor quality medicines in some parts of Asia and Africa. (44). Most of them have been shown to contain sub-therapeutic amounts of the active pharmaceuticals or no API at all or even toxic compounds.( 45,46,47,48)

A survey found 38% of tablets sold in five countries in mainland southeast Asia as the anti material Artesunate were fake(25). There were 771 reports of counterfeit drugs with 78% of those coming from developing countries between 1984-1999. The International federation of

pharmaceutical manufacturers associations(IFPMA) has estimated that 7% of all drugs sold around the world are counterfeit (49). From January 1999 to October 2000, 46

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reports of counterfeit drugs were received from 20 countries, 60% from developing countries and 40% from developed nations.(49).

Specialists estimate that, for each drug, on average 30% of the patients experience benefits, 30% do not experience any major benefits, 10% only experience side effects and 30% discontinue treatment because they have either no benefits or side effects(50). Often, the blame for the lack of effective treatment is attributed to the use of generic drugs. Other authors estimate the frequency rate of adverse reactions as 20% of cases and increase the likelihood of adverse reactions to 40% in patients who need to receive more than 15 drugs per period of hospitalization(51). The global picture, over 80% of participants believed that generics are relatively less safe for use than branded equivalents in a recent survey.(52), conducted in Maharashtra, India.

Country of origin is often associated with product quality(53). Consumers may use a country's reputation to predict the quality of products(53). The multidimensional effect of country of origin image influences product beliefs and attitudes for brands with different levels of equity. (54)

Over 23% of physicians surveyed expressed negative perception about efficacy of generic drugs, almost 50% reported negative perception about quality of generic medications and more than quarter do not prefer to use generics as first line medications for themselves or for their family(7).

Despite the fact that 83% of the clinicians claimed to practice RUM(rational use of medicines), only 15% wrote the generic name of the drug, only two could write parts of the prescription correctly, and only 71.4% of the clinicians complete knowledge of ingredients of the medicament prescribed. The pharmaceutical company representatives(75%) and medical journals(42%) were the most common sources of information about generic drugs(58).

Full awareness about the adverse effects, interactions and contradictions of the drugs being prescribed was lacking in 32% of the clinicians(8). The prescribing patterns of prescribers have severally been studied as a direct influencing factor on the rational use of medicines worldwide. With the WHO estimating that more than half of all medicines being prescribed, dispensed, or sold inappropriately(55). A systematic review analyzing 52 articles revealed that a noteworthy number of doctors were concerned about the efficacy, safety and quality of generic medicines causing more adverse effects(56). One Greek study reported that the national initiative for generic prescribing has been poorly endorsed by the physicians of the country(57).

### **Few examples of adverse reactions:**

1) Procrit, a drug used by cancer and AIDS patients to fight fatigue and anaemia, was counterfeit in 2002, counterfeit watered down the medicines with non sterile tap water to one twentieth of the strength listed on the label. The tap water posed a risk of infections in already weak patients(24)

2) Another recently counterfeit drug was Epogen, a drug used to treat several anaemia. Counterfeiters also watered down this medication and reduced its effectiveness in patients' bodies.(24)

3) In summer 2003, nearly 2,00,000 tablets of the cholesterol reducing medication lipitor were found to be fake and recalled(24).

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4) In 2006, in the UK the drug lipitor was found to have been lacking the sufficient quantities of API(25)

5) The consumption of paracetamol cough syrup made up of diethylene glycol(a toxic chemical used in antifreeze) led to 89 deaths in HAiti in 1995 and 30 infant deaths in India 1998(25).

6) In 2007, North Carolina Public Radio's. The people's pharmacy began reporting on consumer's complaints that generic versions of bupropion(wellbutrin)were yielding unexpected effects(59), subsequently, Impax laboratories' 300 gm extended release tablets, marketed by Tene Pharmaceutical Industries, were withdrawn from the US market after the FDA determined in 2012 that they were not bio equivalent.(60,61)

7) Two women, each claiming to have suffered severe medical complications from a generic version of metoclopramide, lost their supreme court appeal on june 23, 2011. Ina 5-4 ruling PLIVA, Inc.v. mensing(62,63) in which the court held that generic companies can not be held liable for information, or the lack of information, on the originator's label(64,65,66).

8) In 2001, in the netherland 83% of hospital admissions had the main cause an adverse drug reactions, 6% of these patients died(67)

9) The 2014 episode of death of 13 women and illness of 138 following tubectomy and prescription of poor quality ciprofloxacin is a clear indication of the deficiencies in our system which makes available poor quality medicines(4).

10) One instance of disregard of GMP by an Indian manufacturer, forced the European Medicines Agency committee for medicinal product of Human use to recall all the batches of generic clopidogrel(68).

### **Reasons influencing doctors to prescribe branded drugs, Identified through secondary data, literature review and observations**

- a. Negative perceptions especially among doctors and pharmacist
- b. Adverse reactions or lack of efficacy,quality
- c. Lack of confidence about quality due to corruption of employee
- d. Doctors developed faith in brands
- e. Influences of branded medicines
- f. Marketing Influences
- g. Counterfeit, fake and spurious drugs
- h. Regulatory mechanism
- i. Patient's reluctance
- j. Rational use of medicines are not there in India or very less
- k. Lack of good manufacturing practice
- l. Malpractices by the doctors
- m. Generic drugs spends very less to market its product
- n. Effect of country of origin
- o. Cost unawareness to the doctors
- p. Therapeutic reasons

**a . Negative perceptions of doctors towards generic drugs:** The negative perceptions of doctors are the principal obstacles for wider acceptance of generic medicines

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both at individual and community level(56). Older physicians exhibited demonstrably worsen perception of generics than did younger physicians over the age of 55 years reported 3-7.5 times more negative responses about generics than did physicians under 35 years(7).

**b . Adverse reactions or lack of efficacy :** Doctors accuse individual variability or lack of quality of generic drugs for adverse reactions or lack of efficacy. The doctor's clinical reasoning should be based on many certainties. Doubts about the effect of insufficient efficacy or toxicity of a generic drug make things more confusing. Many of the doubts concerning the effectiveness of different generic drugs compared with the original are assigned to the excipients. Moreover, “ different salts,esters,ethers,isomers,mixtures of isomers, complexes or derivatives of active substances are considered the same active substance, if not show significantly different properties in terms of safety and/or efficacy(69).

**c . Lack of confidence about quality due to corruption :** The major reason why doctors may not prescribe unbranded generic medicines is the lack of confidence in their quality(70). Corruption and inducement that often lead to substandard medicines being sold in the market remain a major concern.A series of scandals around the approval of generic drugs in the late 1980s shook public confidence in generic drugs.There were several instances in which companies obtained bioequivalence data fraudulently, by using the branded drug in their tests instead of their own product and congressional investigation found corruption at the FDA, where employees were accepting bribes to approve some generic companies' applications and delaying or denying others(71,72,73). A famous parliamentary committee on the functioning of the CDSCO(which oversees the drug approval in India) in 2012 observed that many favourable opinions submitted by experts on trials of the drugs were actually based on their personal perception without any scientific evidence and these opinions were actually written by the invisible hands of drug manufacturers(21).

**d . Doctors developed faith in brands :** Few doctors prescribe branded drugs as they developed faith in those particular brands of drugs or have trust in pharmaceutical companies, manufacturing or marketing those drugs, but quite often the doctors are simply ignorant about the availability of cheaper generic alternatives of costly branded generics or are unaware about potential savings on prescription of cheaper generic drugs or unbranded generics(74).

**e . Influences of branded medicines :** A brand has a certain personality that gives additional values of the product versus the competition(75). There is no doubt that branded medicines have exercised tremendous influences in medicines utilization, but generic drugs being bioequivalent to their brand name counterparts, are considered safe as well as cost effective(76). A study in the USA found that of 43 editorials in scientific journals, 53% expressed negative views concerning generic substitutions for branded cardiovascular disease pharmaceuticals(77), mainly due to advertising by brand companies against generic medicines as well as some generic medicines scandals.

**f . Marketing influences:** It was found that physicians are motivated by pharmaceutical companies' promotional tools to prescribe promoted drugs. Similarly, some

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other studies found a direct correlation between physicians' prescribing patterns and pharmaceutical promotional tools(78,79,80). Trust and quality image of a pharmaceutical company are the important ones among the several factors that influences physicians' prescription behavior(81).

**g . Counterfeit/fake/spurious Medicines** : Drug counterfeiting has become a deliberate issue in India as the country is still required to produce sufficient credible data to prove and ascertain that these counterfeited drugs are posing mounting risk to humanity(27). Counterfeit products may include the wrong ingredients, without active ingredients, missing key ingredients, with insufficient active ingredients, improperly labeled, stored or handled with fake packaging.(26)

Counterfeit drugs are dangerous, a person is at risk for serious health problems, including unexplained side effects or allergic reactions. And the health could worsen if the 'drug' you are taking is ineffective(26).

The business of drug counterfeiting is booming in India because of various reasons such as(26)

- Growing pharmaceutical industry
- Poor manufacturing regulation
- High drug prices
- Prescription of drugs without registration doctors
- Lack of public awareness
- Weak enforcement of legislation and
- Flexibility in the current legal framework

**h . Regulatory Mechanism:** In India, the main concern raised by professional bodies is that the quality regulatory mechanism is weak and variable across status. This may have an adverse impact on health outcomes. Large generic manufacturers that have made India the pharmacy of the world have to meet international standards of quality, but other manufacturers' catering to the domestic market may not be meeting these quality standards(19).

Although there are a number of laws and regulations for ensuring safety in the manufacture and sales of medicines, as well as for prevention of spurious and fake drugs, their enforcement become difficult due to various reasons such as(28)

- Shortage of trained staff and inadequacy of testing facilities (28)

- There is also the question of affordability and easy availability and reliable and safe generic medicines as compared to the costly branded medicines that are more prone to being counterfeit or fake.(28) - CDSCO is grossly understaffed to perform its assigned duties of protecting the general population from substandard, spurious and counterfeit medicines(4)

**i).Patient's reluctance:** The switch from a brand name to generic drug may prove more of a challenge for certain patient groups than others.For example, elderly patients and polypharmacy users can easily become confused, especially since the new product can differ in shape, taste and color(82,83). When patients are switched from a brand to generic drug or between 2 generics, they sometimes complain of adverse events or state their drug is not working as well. It is always attribution to patient anxiety or happenstance(3). Many a times,

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patients may have adverse drug reactions (either due to allergies to excipients or due to nocebo effect- negative symptoms elicited by negative expectation by the patients) or may feel depressed (due to inferior complex) and so deteriorates as a BD is changed to a GD with or without his/her approval(84,85). Despite the fact that more than 2/3rd Indian earn less than \$2 per day, (World development indicator 2014), India is not a poor country. Many patients may not like the idea of getting a cheap drug especially when they have already spent a lot of time and money on transportation, consultancy and or laboratory investigations(84,85). Quite often, if the patient had a poor experience with a generic drug, and so they are biased towards branded medications and are willing to pay a higher price(86).

**j . Rational use of medicines are not there in India or very less:** For the propagation of RUM in India, the All India drug Action network was founded in 1982, since then, it has been active in the campaign for RUM. Despite the fact that 83% of the clinicians claimed to practice RUM (rational use of medicines), only 15% wrote the generic name of the drug, only two could write parts of the prescription correctly, and only 71.4% of the clinicians complete knowledge of ingredients of the medicament prescribed. Full awareness about the adverse effects, interactions and contradictions of the drugs being prescribed was lacking in 32% of the clinicians(8). There is a tendency of many physicians to prescribe the latest medicines in preference to earlier ones(13). Doctors tend to prescribe what they know and are hesitant about prescribing generics(13). Prescribing habits of physicians has been shown to be influenced by several factors such as peer influence, financial considerations, activities of pharmaceutical representatives and advertising in journals and medical literature(11).

**k . Lack of good manufacturing practice:** Lack of GMP by pharmaceutical companies has been a major concern and biased doubts regarding the efficacy and safety of generic medicines(68). Ideally, all factories manufacturing GDs as well as BDs must follow the rules of GMPs; but this is seldom true in Indian scenario. It is also revealed that many generic IP companies have set-up separate manufacturing units for supply to the western countries and for supply to the third world countries. These practices need to be abolished immediately(21).

**l . Malpractices by the doctors:** Cost of medicines to consumers is often commented upon by pharmaceutical nexus, a troubling state of affairs. Some doctors are reported to receive substantial incentives from pharmaceutical companies to prescribe the products of these companies. The patients are financially impacted only to the extent that these incentives are hidden costs in drug pricing(9). Moreover, there was heavy reliability and dependence on MRs for drug information.

**m . Generic drugs spend very less to market its product:** Generic industry spends very little to market its products while patented drug firms encourage marketing and detailing. This results in a continuing state of negative perception towards generic drugs(13).

**n . Effect of country of origin:** It has been observed that country of origin influenced consumers' overall perception of brand and there were differences in influences across highly reputed brands and comparatively less reputed brands. Brand origin is found to be of significant impact on brand image perception. There are a number of examples when the product is manufactured in a country with comparatively lower images than the country of brand origin, country of manufacturer information produces significantly negative effect on evaluation of products(87)

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**o . Cost unawareness to the doctors:** A study conducted by Tim Schuttee and his fellow friends in August 2016, pointed to this issue that medical students and doctors seem unaware of the cost of drugs they frequently prescribe. The cost of the generic drugs tends to be overestimated and that of proprietary drugs underestimated(12).

**p . Therapeutic reasons:** Doctors faced problems while prescribing medicines with a narrow therapeutic index(NTI). The bioavailability of such medicines may vary between two different manufacturers and lead to clinically significant implications ranging from therapeutic failure to drug toxicity. In some classes of medications, generic substitution is controversial.

**Narrow therapeutic index(NTI)** drugs are medications with a small threshold between effective and toxic doses. This means minor variations in the percentage of drug exposure may lead to serious adverse outcomes.(Demystifying generic substitution: 2013, Paveliu MS,2011, from the literature of Kendra R,2017). The European Medicine Agency(EMA) recommends that the accepted CI for the Cmax and AUC be narrowed to 90% to 111.11% for NTI drugs. (Pierini D, 2013)Generic substitution is also of particular concern with **antiepileptic drugs (AEDs)**. Bioequivalence may be compromised in AEDs with low water solubility. (Generic substitution of antiepileptic drugs;2007).

**Conclusion :** The negative opinion of physicians concerning cheaper equivalents may be an important barrier to the use of cheaper drugs, which was given as one of the key causes of the considerably smaller sale of generics(26)(98 lit). In Spite of encouragement from policymakers, generic drug use in India is yet to gain widespread popularity, and the practice so far has remained confined mostly to institutional settings in small pockets of the country. Consumers might use country of origin because quality can not be determined until a product is actually consumed, that is country of origin is used in place of missing product information. There is a need to continuously study the factors that influence the prescribing habits of prescribers with the aim of decreasing the economic waste and morbidity(2)(1 lit). In this era of increasing healthcare budget constraints, we think cost awareness is important to therapeutic reasoning and cost-effectiveness prescribing.(85 lit). There is significant fractions of physicians' expresses their apprehensions about the efficacy and quality generics, and especially senior physicians have definite trepidation(39) (69 lit).The existence of several generic alternatives to a branded product leads to challenges for patients. Concerns for the replacement of those original with copy medicines are linked to a certainty: large studies certify their efficacy and safety for brand drugs, while for generics efficacy and safety is only presumed. ( 41 lit). One concern about substitution of NTI medication and AEDs is the switching a stable patient to a medication that may not produce the same effects could potentially cause the patient harm, thereby outweighing the possible cost savings associated with these medications.(Kendra R,2017). The brand personality and quality image of the product were the key factors that created a status for the drug. Medical representative visit, key opinion leader source effect and age of the product as the major influences apart from the internet, academic papers, advertising recall and patient preference.

**References and Bibliography :**

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## E-Journal of Research

ISSN NO: 2395-339X

1. Sanyal SN., Datta SK., Banerjee AK., (2017), Factors influencing prescribing decision among physicians: an empirical study on generic drugs. *International Journal of pharmaceutical and Healthcare Marketing*, 11(4), 330-360.
2. Das M., Choudhury S., Maity S., Hazra A., Pradhan T., Pal A., Roy R., (2017), *Generic Versus branded medicines: An observational study among patients with chronic diseases attending a public hospital outpatient department. Journal of natural science, Biology and Medicine*, 2017;8: 26-31
3. Michael white C., (2019), Generic Drugs Not as Safe as FDA Wants You to Believe. *Annals of Pharmacology*, 1-4.
4. Dhamija P., Sharma PK., Kalra S., (2015), Only generics (drugs/names) : Is India Ready?. *Indian Journal of Endocrinology and Metabolism*, 19(5), 541-546.
5. Mohamed A.A., Hassali, Asrul A., Shafie, Shazia Jamshed, Mohamed I.M., Ibrahim, Awaisu A., (2009), Consumers' views on generic medicines: a review of the literature. *International Journal of Pharmacy Practice*, 2009; 17: 79-88.
6. Roy V., Rana P., (2018), Prescribing generics : All in a name. *Indian Journal of Medical Research* 147, May 2018: 442-444.
7. Shrank Wh., Liberman JN., Fischer MA., Girdish C., Brennan TA., Choudhry NK., (2011), Physician Perceptions about Generic Drugs. *The Annals of Pharmacotherapy* ;2011 January, volume 45: 31-37.
8. Mahajan R. (2010), Current scenario of attitude and knowledge of physicians about rational prescription : A novel cross-sectional study. 2(2) : 132-136.
9. Andrade C., Roa Sathyanarayan TS., (2017). Prescription writing: Generic or brand ? *Indian Journal of Psychiatry* 59(2): 133-136.
10. Lewek P., Śmigielski J., Kardas P., (2015), Factors affecting the opinions of family physicians regarding generic drugs- a questionnaire based study. *Bosnian journal of basic medical science* 15(1) : 45-50.
11. Yaw A., Ofori-Adjei, Fiakpornoo M., (2019). The influence of physicians' speciality on prescribing patterns at a general medicine out-patient clinic. *Ghana Med J* 53(3): 204-209.
12. Schutte T., Tichelaar J., Nanayakkara P., Richir M., Agtmael Mv., (2017), Students and Doctors are Unaware Of the cost of Drugs they Frequently Prescribe. *Basic & Clinical Pharmacology & Toxicology*, 120, 270-283.
13. Ernest Cyril de Run, Mee-Kon Ng Felix, (2006), Patented And Generic Pharmaceutical Drugs : Perception and Prescription, *International Journal of business and Society* 7(2), 55-78.
14. Toverud E-L, Hartmann K., Hakonses H., (2015), A Systematic Review of Physicians' and Pharmacists' Perspectives on Generic drug Use: What are the Global Challenges?. *Appl Health Econ Health Policy* 13(1); 835-845.
15. Manigault K., Marcheiva G., Peasah S., (2016), Insights Into Effective Generic Substitution. *U.S. Pharmacist, The pharmacist's Resource for Clinical Excellence*, 41(6) 29-33.
16. Sreerexha Ch., Venkataswamy M., Manasa Y., Boppana R., Kadannagari S., Kilari S., (2019), Generic Drugs a Benison to Mankind. *Research Journal of Pharmaceutical Dosage Forms and Technology*. 11(2): 121-125.

# Saarth

## E-Journal of Research

ISSN NO: 2395-339X

17. Paveliu M., Bengea S., Silvia F., (2011), Generic Substitution Issues : Brand-generic Substitution, Generic-generic Substitution, and Generic-Substitution of Narrow Therapeutic Index (NTI)/Critical Dose Drugs. *Medica-a journal of clinical medicine*, 6(1), 52-58.
18. Nagargoje MM, Chaudhary SS, Siddiqui HA, Misra SK, Garg SK, (2017), Generic drugs for public health in India : unbranded versus branded generics. *MRIMS Journal of Health Science*, 5(2), 48-52.
19. Dixit A., Kumar N., Kumar S., (2018), *Use of Generic Medicines: Challenges and Benefits. Journal of Health Management*;20(1):84-90.
20. Khazzaka M.,(2019) ,*Pharmaceutical marketing strategies' influence on physician' prescribing pattern in Lebanon: ethics,gifts, and samples. BMC Health Services Research*;19:80.
21. Nagargoje MM, Chaudhary SS, Siddiqui HA, Misra SK, Garg SK, (2017),*Generic Drugs for public health in India.....Advantage India. MRIMS Journal* 5(1), 1-5.
22. Shamindra Nath Sanyal, Saroj kumar Datta, (2011), *The effect of country of origin on brand equity: an empirical study on generic drugs. Journal of Product and Brand Management* 20/2, 130-140
23. Haque M., (2019), *Generic Medicine and prescribing: A Quick Assessment. Adv Hum Biol* 2017; 7:101-8.
24. Yadav D.,(2015), *Spurious Drugs/Counterfeit Drugs-An Overview. PharmaTutor*;3(10):13-15.
25. Yadav S., Rawal G., (2015), *Counterfeit drugs: problem of developing and developed countries. International journal of Pharmaceutical Chemistry and Analysis*;2(1):46-50.
26. Verma S., Kumar R., Philip P.J.,(2014), *The Business of counterfeit Drugs in India: A Critical Evaluation. International Journal of Management and International Business Studies*;4(2):141-148.
27. Muhammad M., Mohammad NH., Chrysostome E., Zhan Su, (2017), *Relocating high-tech industries to emerging markets: case of pharmaceutical industry outsourcing to India, Transnational Corporation Review.*
28. Mishra B.,(2012),*The Partnership for safe Medicines- India: Lessons for Partnerships in Emerging Markets. Journal of Commercial Biotechnology*1;8(4):36-39.
29. *US food and drug administration, Available from <http://www.fda.gov/drugs/resourcesfor you/consumer/buying using medicine safely/understanding generic drugs/default.htm>.*
30. *Note for guidance on the investigation and bioequivalence. The European Agency for the Evaluation of Medicinal products. London 14.12.2000. CPMP/EWP/QWP/1401/98. Available from [http://www.erna.europa.eu/docs/en\\_GB/document\\_library/scientific\\_guideline/2009/09/WC 50 0003519.pdf](http://www.erna.europa.eu/docs/en_GB/document_library/scientific_guideline/2009/09/WC 50 0003519.pdf)*
31. *Guidance for Industry Bioavailability and Bioequivalence Studies for Orally Administered Drug Products- General considerations. US department of Health and Human Services Food and Drug Administration Centre for drug education and Research (CDER) March 2003. Available from: <http://www.fda.gov/downloads/Drugs/GuidancecomplianceRegulatoryinformation/Guidances /UCM070123.pdf>*

# Saarth

## E-Journal of Research

ISSN NO: 2395-339X

32. World Health Organization. Global Health Observatory(GHO) data. Out-of-pocket expenditure on health as a percentage of private expenditure on health(US\$). Available from: [http://www.who.int/gho/health\\_financing/out-of\\_pocket\\_spending/en/](http://www.who.int/gho/health_financing/out-of_pocket_spending/en/)
33. Hakonsen H, Horn AM, Toverud EL. Price control as a strategy for pharmaceutical cost containment- what has been achieved in Norway in the period 1994-2004? *Health Policy* 2009;90(2-3):277-285.
34. Hakonsen H, Toverud EL. A review of patient perspective on generic substitution: what are the challenges for optimal drug use? *GaBI J.* 2012;1(1):28-32
35. Ojikuta B, Jack C, Ramjee G. Provision of antiretroviral therapy in South Africa: unique challenges and remaining obstacles. *J infect dis.*2007;196(Suppl 3):S523-7.
36. Carroll NV. Impact of generic and therapeutic interchange incentives on community pharmacy. *Am Pharma* 1995; NS35(7):27-34.
37. Karim SS et al. Potential savings from generic prescribing and generic substitution in South Africa *Health Policy Plan* 1996;11(2): 198-205.
38. Kirking DM et al. Economics and structure of the generic pharmaceutical industry. *J Am Pharm Assoc(wash)* 2001; 41(4):578-584.
39. Zora M, Harris A, Tobe LA, Siesky B, Januleviciene I, Behzadi J et al. Generic medication in ophthalmology. *Br J Ophthalmol* 2013;97(3):253-7.
40. United States Congress. Senate. Committee on Health Education Labor and Pensions. Generic drug user fee amendments: accelerating patient access to generic drugs: hearing of the Committee on Health, Education, Labor, and Pensions, United States Senate, one Hundred Fourteenth Congress, second session on examining generic drug user fee amendments, focusing on accelerating patient access to generic drugs, January 28, 2016. Washington, DC: U.S. Government Publishing Office,2018.
41. Havocscope (2013). "Estimated value of the fake drug industry", available at: <http://www.havocscope.com/estimated-value-of-the-fake-drug-industry>.
42. Bate R, Boateng K Bad medicine in the market. *Am. Enterprise Inst. Public Policy Res.* 2007; 43:13-21.
43. Raufa A. India agrees to help Nigeria tackle the import of fake drugs. *Br. Med. J.*2003; 326:1234.
44. Chiks A, Bello SO, Jimoh AO, Umar MT. The Menace of Fake Drugs: Consequences, Causes and Possible Solutions. *Research Journal of Medical Sciences.* 2011; 5(5):57-261.
45. Newton PN, White NJ, Rozendaal JA, Green MD. Murder by fake medicines, *BMJ.* 2002; 324:800-1.
46. Nayyar GML, Breman JG, Newton PN, Herrington J. Poor quality antimalarial medicines in southeast Asia and sub-saharan Africa. *Lancet Infect Dis.* 2012; 12:488-96.
47. Maponga C, Ondari C. The quality of antimalarial; a study in selected African countries. World Health Organization (WHO) Department of essential medicines and medicines. WHO/EDM/PAR/2003. 4:2003. Available from URL: <http://apps.who.int/medicinedocs/pdf/s4901e.pdf>
48. Chikowe I, Osei-Safo D, Harrison J, Konadu DY, Addae-Mensah I. Post-marketing surveillance of antimalarial medicines used in Malawi. *Malar J.* 2015; 14:127.
49. Gupta P, Singhal K, Pandey A. Counterfeit(Fake) Drugs & New Technologies to identify it in India. *Int J Pharm Sci Res.* 3(11): 4057-4064.

# Saarth

## E-Journal of Research

ISSN NO: 2395-339X

50. Rumel D, Nishioka Sde A, Santos AA. Drug interchangeability: clinical approach and consumer's point of view. *Rev Saude Publica* 2006;40.
51. *Harrison's Principles of Internal Medicines, McGraw-Hill Professional; 17 editions, 2008.*
52. Ahire K, Shukla M, Gatani M, Singh V, Singh M. A survey-based study in the current scenario of generic and branded medicines. *Int J Pharm Pharm Sci* 2013;705-11.
53. Lusk, J.L, Brown, J., Mark, T., Proseku, I., Thompson, R. and Welsh, J. (2006), "Consumer behaviour, public policy, and country-of-origin labelling":, *Review of Agricultural Economics*, Vol. 28 No2, pp. 284-92.
54. Hui, K.M. and Zhou, L. (2003), "Country of manufacturer effects for known brands", *European Journal of Marketing*, Vol. 37 No.1/2, PP. 133-53.
55. Hogerzeil HV. Promoting rational prescribing: an international perspective. *Br J Clin Pharmacol* 1995; 39(1): 1-6.
56. Colgan S, Faasse K, Martin LR, Stephens MH, Grey A, Petrie KJ. Perceptions of generic medication in the general population, doctors and pharmacists: A systematic review. *BMJ Open* 2015;5:e008915.
57. Labiris G, Fanariotis M, Kastanioti C, Alexias G, Protopapas A, Karampitsakos T, et al. Greek Physicians Perceptions on generic drugs in the era of austerity. *Scientifica(Cairo)*2015:251792.
58. Hodges B. Interactions with the pharmaceutical industry experiences and attitudes of psychiatry residents, interns and clerks. *CMAJ* 1995;153(5):553-9.
59. "Drug Tests: Wellbutrin vs. Generic Bupropion". 2012-12-06. Retrieved 20.
60. Healy, Melissa(2012-10-05). "Generic antidepressant pulled from U.S. shelves after FDA finding". *Los Angeles times*.
61. FDA Update: Budeprion XL 300 mg". *US. Food and Drug Administration* 2012-10-03.
62. "PLIVA, Inc. v. Mensing - SCOTUSblog.
63. Supreme Court of the United States 564 PLIVA, Inc. v. Mensing U.S.(2011).
64. Adam Liptak for the New York Times. June 23,2011 Drug Makers Win Two Supreme court Decisions.
65. Steven Casey for Law360. October 24, 2012 Generic Pharmaceutical Liability: Challenges and Changes.
66. [http://www.diffen.com/difference/Brand\\_Name\\_Drugs\\_vs\\_Generic\\_Drugs](http://www.diffen.com/difference/Brand_Name_Drugs_vs_Generic_Drugs).
67. Van der Hooft CS, Sturkenboom Mc, van Grootheest K, et al-Adverse drug reaction-related hospitalisations: a nationwide study in The Netherlands. *Drug Saf.*2006;29:161-8.
68. Pavelin MS, Bengea S, Paveliu FS. Generic substitution issues: Brand-generic substitution, generic-generic substitution, and generic substitution of Narrow Therapeutic Index(NTI)/critical dose drugs. *J Clin Med* 2011; 6: 52-8.
69. Law no. 95/2006 on health reform.
70. Rana P. Roy V. Generic medicines: Issues and relevance for global health. *Fundam Clin Pharmacol* 2015; 29: 529-42.
71. Freudenheim, Milt(10 september 1989). "Exposing the F.D.A." *New York Times*.
72. Andrews, Edmund L.(31 july 1989). "FDA Inquiry on Generic Drugs Focuses on Changes in Ingredients". *The New York Times*.

# Saarth

## E-Journal of Research

ISSN NO: 2395-339X

73. Pereira JA, Halbrook AM, Dolowich I., Goldsmith C, Thabane L, Douketis JD, Crowther MA, Bates SM, Ginsberg JS(2005). “ Are brand names and generic warfarin interchangeable? Multiple n-of-1 randomized, crossover trials”. *Ann Pharmacother.*(7-8):1188-93.
74. Thakur VPS and Ramacha S. *Pharmaceutical Business Strategy: A Generic Perspective. Journal of Intellectual Property Rights.* 2012, 17(Sept):484-496.
75. Kapferer J-N(2011), *The New Strategic Brand Management: Creating and Sustaining Brand Equity long term*, Kogan Page New Delhi.
76. Pearce GA et al. *Bioequivalence: how, why, and what does it really mean? J Pharm Pract Res* 2004; 34: 195-200.
77. Kesselheim, A.S., Misono, A.S., Lee, J. L., Stedman, M.A., & shrank, W.H.(2008). *Clinical equivalence of generic and brand name medicines used in cardiovascular disease: A systematic review and meta-analysis.* *JAMA*, 300(21), 2514-2526.
78. Van den Bulte C, Lilien GL. *Medical innovation revisited social contagion versus marketing efforts.* *Am J Social.*2001;106(5):409-35.
79. Narayana S, Manchanda P, Chintagunta PK. *Temporal differences in the role of marketing communication in new product categories* *J Mark Res.* 20054;42(3):278-90.
80. Hahn M, Park S, Krishnamurthi L, Zoltners AA. *Analysis of new product diffusion using a four-segment trial repeat model.* *Mark Sci* 1994, 13(3):224-47.
81. Moss, G.D. and Schuiling, I. (2008), “A brand logic for pharma? A possible strategy based on FMCG experience”, *Journal of Medical Marketing*, Vol. 4 No.1, pp.55-62.
82. Hakonsen H, Eilertsen M, Borge H, Toverud EL, *Generic substitution: additional challenge for adherence in hypertensive patients? Curr Med Res Opin.*,2009;25(10):2515-21.
83. Hakonses H, Toverud EL., *Special challenges for drug adherence following generic substitution in Pakistani immigrants living in Norway.* *Eur J Clin Pharmacol.* 2011;67(2):193-201.
84. Gavura Scott (2012). *Generic Drugs: are they Equivalent?* Posted on January 5,2012 on: <http://www.sciencebasedmedicine.org/genericx-drugs-are-they-equivalent/>
85. Friedman Lauren. *Here’s why you should always buy generic drugs.* Article posted on May 6, 2104, on the website of business insider and accessed.
86. Bera A and Mukherjee A. *The importance of generic drugs in India.* *IJPCBS.* 2010,2(4): 575-587.
87. Koubaa, Y. (2008), “Country of origin, brand image perception and brand image structure”, *Asia Pacific Journal of Marketing and logistics*, Vol 20 No. 2, pp.139-55.