

An awareness on generic medicine with reference to commerce students of Loyola College Vettavalam

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Abstract

Anything for the poor is always a welcome idea but not at the cost of human health and endurance. The tier of generics versus branded linctus is not new phenomenon. Timely use of medicines can safeguard operational treatment of many ailments and duck the need for costly treatment for patients. Suggestively, generic medicines can treat many illnesses today effectively. There is no hesitation that branded medicines have drilled tremendous influence in medicine field, but generic drugs being bioequivalent to their brand-name counterparts, are considered safe by substantially sinking costs to health care budgets and patients. The quality of the product depends on the complex processing and manufacturing of a research molecule. Universally, the use of generic drugs has increased progressively because of economic pressures on drug budgets.

Keywords: human health and endurance, generic medicines, generic drugs

Introduction

A drug is a chemical element, which is used to treat or diagnose a disease. Its takes many years to discern a new drug as has to undergo many clinical trials. Only if the drug is approved by the USFDA standards it is legalized to be manufactured in the pharma industries and gets the patent. As the drug, research is highly expensive and not affordable by public, due to this reason the generic drugs was introduced. A generic drug is a pharmaceutical drug that is equal to a brand-name product in dosage, strength, route of administration, quality, performance, and intended use. They are commonly subjected to government protocols in the nation state where they are distributed. A generic drug must encompass the same ingredients as that of original brand-name origination.

With the mushrooming of pharma companies, the drug control mechanisms in India have huge precincts both in terms of availability of manpower and technology. The drug license is obtained through political or bureaucratic networking by rampant corrupt means. There is a lack of stringent quality control and periodic monitoring due to non-availability of competent pharmacist and dispensers on the medical shops. The pharmacist by and large outsources license and takes his commission out of the contract. The pharmacies across India are largely operated by unemployed and untrained youth or family members. Further, many drug formulations with combinations shall be difficult for the unqualified shopkeeper to deliver.

Statement of the Problem

There is a realistic need to create awareness among the college students of our country in regard to Generic Medicine to disseminate the information to the common masses as budding educators and change agents with noble intentions and let the poor people avail the benefits at large rather than a game of profiteering.

Objectives

The study has the following objectives.

1. To understand the concept of Generic Medicine.
2. To analyze the various pros and cons of generic medicine.
3. To create awareness about generic medicine and its availability.

Review of Literature

Aliya Moin*, Sowjanya M, Department of Pharmaceutics, Adhiparasakthi College of Pharmacy, Melmaruvathur, Kancheepuram, Tamil Nadu stated that over the last few years even our country has developed in producing quality generic drugs in most of the thereupatic categories. However, these generic drugs are available at reasonable prices but still most of the population of our country is still unable to afford these drugs. In our country, generic drugs are developed in most of the therapeutic categories. Even though, these generic drugs are made available at reasonable prices, most of the population is still unable to access the generic drug usage. So, in order to make it available to layman, the government has introduced the Jan Aushadhi Scheme, making the availability of generic drugs and helping to get medicines at affordable prices. This Jan Aushadhi stores are presents all over the country enabling the availability of drugs at reasonable prices having 600 plus drugs. The Jan Aushadhi stores are licensed under the roof of pharmaceutical products of India.

World Health Organization estimates that almost 30% of the world population lacks access to essential medicines and that the figure will rise to more than 50% in some countries of Africa and Asia. The cost of the pharmaceuticals is the main factor that hampers access to medicines and the governments in poor countries seem to be doing very little to counter this problem. The public sector availability of essential medicines was less than 50% in most of the countries of Africa and Asia. This is appalling in the face of increases in healthcare expenditure in most of the developing nations, mostly

financed through secured loans by international development banks and consortia. The situation in India is not very different than that of other developing nations. Healthcare expenditures have been growing in India, both in real terms and also when considered as a proportion of the Gross Domestic Product (GDP). However, even with this recent increase in healthcare spending, India's expenditure on health is nowhere near that of OECD (Organization for Economic Cooperation and Development) nations. The total public spending on healthcare in India accounted for only around 1.2% of GDP in 2012, with the per-capita spending on health around USD 160. This is a miniscule amount when compared against the OECD per-capita healthcare spending of USD 3,484 in 2012. This shows that the healthcare spending in the country is set to rise further in the coming years and the healthcare industry is all set for a boom time. The cost of medicines and pharmaceuticals as a percentage of total healthcare spending has also been rising worldwide. It is the fastest-growing item in the healthcare budgets worldwide and it varies between 20-60% in various healthcare budgets of countries. By 2020, the prescription drug market in United States of America is set to grow to USD 700 billion (B) and China will be USD 260 B. Though no credible predictions about the Indian pharmaceutical industry are available, it is quite safe to assume that Indian pharmaceutical industry will also grow manifold. The growth of the pharmaceutical market worldwide and its increased share in total healthcare spending will reignite the age-old debate on how to balance the cost of innovation in drug research and universal access to the fruits of that research.

Pushpagiri Medical College, which is a teaching hospital in Kerala state of India partnered with a social organization, Bodhana Social Service Society, involved in poverty alleviation and income generation programmers, to start an urban health center with an objective to improve patient accessibility to cost-effective medical care. The urban health center serves a population of 10,000, spread over 5 municipal wards of Tiruvalla municipality and was intended as a model for cost-effective primary care. A comprehensive population survey was carried out before the start of the project and the health center started functioning in September 2014. As a part of the initiative, a community pharmacy was opened to stock unbranded generic drugs manufactured by two non-governmental organizations. Low-Cost Standard Therapeutics (LOCOST), Baroda and Comprehensive Medical Supplies India (CMSI), Chennai were the two NGOs providing us with the drugs which were needed at the community pharmacy. The drugs were provided to us at a nominal cost, after we provided an undertaking that the Pushpagiri Medical College is a charitable institution with no intention of making profits. Also, the physicians working at the health center made a collective decision to prescribe all the drugs generically and the pharmacist was advised to dispense the cheapest generic brand. The drug inventory available with these not-for-profit manufacturers were fairly comprehensive when reviewed using the World Health Organization-Health Action International (WHO-HAI) tool for quantifying availability of essential medicines. WHO-HAI tool is a validated method for measuring availability of drugs in a health system and includes 30 core medicines: 14 essential medicines for global

burden of disease and 16 medicines specific to the WHO region.

Review of stakeholder opinions: One of the articles found was a comprehensive and clearly presented narrative review, by Hassali *et al.* Which collated international studies published between 1980 and 2008. This article coalesced the collective views of physicians as accepting of generic substitution (GS) under policy and economic pressures, but having concerns regarding the overall quality, reliability and switch ability of generic drugs. This review further theorized that those concerns may prevent full adoption of generic drug prescribing and substitution by physicians, which could lead to escalation in healthcare costs for governments, insurers or consumers directly.

Methodology

Pilot study was conducted. Cronbach's Alpha holds zero. 71 for testing the reliability of the questionnaire. The researcher used questionnaire method as the data collection tool. The data was collected from the students belonging to Department of Commerce of Loyola College, Vettavalam. The present study is based on Simple Random Sampling method. The sample size determination is (n = 60). The research was carried out by using both primary data and secondary data.

Research Gap

Based on preceding literature it is found that studies have been conducted in clinical aspect with high-end computation towards generic medicine. Literature review is found on perception module, attitudes and awareness among the common people, but in regard to the awareness among the college students is lacking. This was the research gap identified by the researcher. The present study is an endeavor to fill the gap and the need of an hour to educate the college students to attain not only knowledge about such social issues prevailing, can enhance them further practically by participating in various social services units and disseminating the information in and around.

Pros and cons of generic medicine

According to the Food and Drug Administration (FDA), generic drugs is a copycat of a brand name drug (created after the patent from the brand name has ended). The following are the benefits of generic medicine:

- 1. Economy:** Brand name drugs require research testing and time consuming process. They only need to copy what already exists, do not have to face the brand name and manufacturing cost allowing the price to stay low.
- 2. Bioequivalent:** Generic drugs must encounter stern guidelines approved by FDA to perform research so that the same amount of active ingredient is delivered as that of brand name medications.

The limitations of generic medicine are as follows:

- 1. Contagion:** Generic drugs are frequently produced in countries like India or China with low-cost labor and overheads. The factory settings have sometimes contaminated drugs.
- 2. Omissions:** According to a report by the Government Accountability Office, these foreign factories sometimes escape rigorous FDA inspections, dodge documentation of

their practices, and don't receive follow-up monitoring even when serious manufacturing or drug-handling problems have been identified. Usually only one manufacturer produces a brand name drug whereas several manufacturers can produce a generic drug. While the FDA insists on bioequivalence of the active drug, there sometimes can be subtle differences in the delivery system of the drug or non-active "fillers" for the drug. These differences rarely result in any clinically meaningful problem for the patient although in rare instances a patient might have a sensitivity or intolerance to a different filler or delivery system.

- 3. **Insurance Coverage:** More patients find their brand name prescription that will not be covered by their insurance plan or their co-pay is higher. Often, the insurer will offer a generic version at a co-pay that is less.

Facts about generic drugs

- FDA recently evaluated 2,070 human studies conducted between 1996 and 2007. These studies compared the absorption of brand name and generic drugs into a person's body. These studies were submitted to FDA to support approval of generics. The average difference in absorption into the body between the generic and the brand name was 3.5 percent. The difference for the generic-to-brand comparison was about the same as the brand-to-brand comparison.
- In 2010 alone, the use of FDA-approved generics saved \$158 billion, an average of \$3 billion every week.
- All generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs, and the generic products must meet the same exacting specifications as any brand name product. In fact, many generic drugs are made in the same manufacturing

plants as brand name drug products.

Application of tools

Percentage Analysis was used to compute the basic milieu of the respondents. To avail the basic information about generic medicine among the commerce students Garrett Ranking Method was calculated manually. In this method, the respondents were asked to rank according to the preferential merit based.

Findings of the study

Milieu of the Respondents: Demographic Profile Variables

Table 1: Age of the Respondents

| S. No | Age (in years) | No. of Respondents | Percentage |
|-------|----------------|--------------------|------------|
| 1. | 17-18 years | 11 | 18.3 |
| 2. | 18-19 years | 27 | 45 |
| 3. | 19-20 years | 20 | 33.4 |
| 4. | Above 20 years | 2 | 3.3 |
| Total | | | 100 |

Source: Primary Data

Table 2: gender of the respondents

| S. No | Gender | No. of Respondents | Percentage |
|-------|--------|--------------------|------------|
| 1. | Male | 40 | 66.67 |
| 2. | Female | 20 | 33.33 |
| Total | | | 100 |

Source: Primary Data

Table 3: Place of the respondents

| S. No | Residence | No. of Respondents | Percentage |
|-------|-----------|--------------------|------------|
| 1. | Rural | 48 | 80 |
| 2. | Urban | 12 | 20 |
| Total | | | 100 |

Source: Primary Data

Table 4: Calculation of Percentile Position

| Variables | Percentile Position | Garrett's Table Value |
|--|---------------------|-----------------------|
| Bio equivalent | 22.32 | 65 |
| Approval of FDA to save 30% as much as to 80% | 35.71 | 58 |
| Jan Aushadh Medical Store | 22.32 | 65 |
| To reduce unethical deliberate prescription of doctors | 7.14 | 78 |
| Promotion and Marketing | 64.28 | 43 |

Source: Primary Data

Table 5: Individual Substitution in Garrett Ranking Conversion Table

| Variables | Total | GT Value | Rank |
|---------------------------|-----------------|----------|------|
| Bio equivalent | 4 18 12 20 6 60 | 65 | 2 |
| Economical | 7 15 24 4 10 60 | 58 | 3 |
| Generic Stores | 8 9 14 7 22 60 | 65 | 2 |
| Illicit unethical doctors | 15 18 17 2 8 60 | 78 | 1 |
| Promotion and Marketing | 4 14 9 16 17 60 | 43 | 4 |

Source: Primary Data

Findings

1. Based on the milieu of the respondents it is found that 45 percentage of the respondents belongs to the age group of 18-19 years.
2. 66.67 percentage belong to the gender category of male

students from department of commerce of Loyola College, Vettavalam.

3. It is noticed from table 1.3 that 80 percentage of the respondents belong to the rural background.
4. From the application of Garrett Ranking it is observed from the above table that by reducing the unethical and intentional practices of doctors by prescribing the branded medicines to the patients is ranked first. This widens the gap between the rich and the deprived and does not serve the real purpose of the poor. The awareness is highly lacking also in terms of bio equivalency and accessibility of Jan Aushadh Store in every district or in the state is ranked second equally. Though 80 percentage of the respondents are from the rural background, yet are not aware about the availability of the generic medicine

neither of generic stores. The third ranked is however cost-effective but the respondents has a doubtful sensation regarding the composition of the generic medicine when compared to branded medicine. The final rank is promotion and marketing activities to be carried out.

Suggestions

1. Regarding the drug pricing, the National Pharmaceutical Pricing Authority can always reduce the maximum retail price and illicit the manipulation practices by the pharma companies.
2. The Medical Council of India has already given strict instructions to doctors to prescribe generic medicines. Strict measures should be adopted so that the doctors are compelled to prescribe generic medicine.
3. Strengthening Jan Aushadhi Scheme.
4. Government could also consider introducing uniform code of marketing for bringing down the cost of medicines. Packaging of the drugs is unattractive in some cases, resulting in difficulty to convince patients about the efficacy of the drug.
5. Advance payment in full has to be remitted to the bank accounts of these NGOs for supply of drugs, which goes against the standard practice of procurement followed in hospitals. This has been an issue with the internal audit department.
6. Absence of intermediaries for drug procurement results in inordinate delays in transit, mainly on account of the tardy services rendered by private logistics companies. This can be improved to a greater extent.
7. The difference between procurement price and the MRP is minimal and this is causing worries of long-term financial sustainability of the community pharmacy model.
8. Steps should be taken to encourage more and more private companies or individuals to open generic drug stores.

Conclusion

Mass consumer awareness about generic medicines is highly lacking due to improper health care professionals, communication run-down and looting the financial incentives. Safety and efficacy issues were viewed as major barriers to the acceptance of generic drug substitutions. The Ministry of Health and Family Welfare should take efforts to embargo the drug stores that do not carry suitable authorization, pharmacists and physicians. Jan Aushadh scheme should be established in interior sub rural areas for making the accessibility of the medicines and can serve the real purpose of the poor. Mandatory availability of generic medicine is to be provided in the Governments hospitals as many poor people prefer going Primary Health care Centres. Educational institutions should take efforts to focus on creating level of awareness, refining the literacy ratio and eliminating the qualms or delusions about generic medications.

References

1. Davit *et al.* comparing generic and innovator drugs: a review of 12 years of bioequivalence data from the United States Food and Drug Administration. *Ann Pharma other.* 2009; 43(10):1583-97
2. Generic Drugs PDF. Center for Drug Evaluation and

- Research, U.S. Food and Drug Administration. Retrieved 23 May 2017.
3. Haas JS *et al.* Potential savings from substituting generic drugs for brand-name drugs: Medical Expenditure Panel Survey, 1997-2000. *Ann Intern Med* 2005; 142(11):891-897.
4. International Journal of Pharmacy Practice Consumers' views on generic medicines: a review of the literature Mohamed A.A. Hassali, Asrul A. Shafie, Shazia Jamshed, Mohamed I.M. Ibrahim and Ahmed Awaisu School of Pharmaceutical Sciences, Universiti Sains Malaysia, 11800 Minden, Penang, Malaysia. 2009; 17:79-88
5. Karim SS *et al.* Potential savings from generic prescribing and generic substitution in South Africa. *Health Policy Plan* 1996; 11(2):198-205.
6. King DR, Kanavos P. Encouraging the use of generic medicines implications for transition economies. *Croat Med J* 2002; 43(4):462-469
7. Kirking DM *et al.* Economics and structure of the generic pharmaceutical industry. *J Am Pharm Assoc Wash* 2001; 41(4):578-584.
8. Lofgren H. Generic drugs: international trends and policy developments in Australia. *Aust Health Rev* 2004; 27(1): 39-48.
9. Medical Definition of Generic drug. Retrieved 23 May 2017.
10. Pearce GA *et al.* Bioequivalence: how, why, and what does it really mean? *J Pharm Pract Res* 2004; 34: 195-200.
11. Williams G, Poynton M. PHARMAC: getting the best bang for your buck since 1993-pharmacy 409 lecture. New Zealand: University of Auckland; Google Scholar. 2009
12. World Health Organization WHO. Generic drugs. Geneva: WHO; <http://www.who.int/trade/glossary/story034/en/index.html>. Accessed 21 June 2015. Google Scholar. 2015
13. <http://www.firstpost.com/india/generic-medicines-in-india-the-myth-and-the-truth-behind-the-healthcare-issue-3413204.html>.
14. <http://www.bcbsm.com/index/health-insurance-help/faqs/plan-types/pharmacy/generic-drug-faq.html>
15. <https://www.verywell.com/generic-drugs-why-they-cost-less-potential-problems-380348>
16. <http://www.cormedicalgroup.com/heart-health-blog/generics>
17. <https://www.quora.com/What-are-the-benefits-of-opting-generic-drugs>
18. <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports>.