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A Review on Generic and Branded Drugs-Competence of Generic Drugs in Comparison to Branded Drugs

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ABSTRACT

The use of generic or branded drug is a great matter of discussion in recent times globally. The government in different countries is also strictly promoting the use of generic drugs in place of branded ones. A generic drug consists of same active ingredient/ingredients as its branded counterpart and found to be equally efficient therapeutically. The cost of generic drugs are much lesser than the branded drugs as they do not need to go through the robust and costly pre-clinical or clinical studies as done in branded ones which increases the cost of them up to many folds. The present review enlightens the effectiveness of generic drugs as compared to branded drugs and how they work in body. An attempt is also made to highlight the cost comparison between both classes, the regulations and control pertaining to generic and branded drugs.

Keywords: Generic Drugs, Branded Drugs, Rational use of Generics as compared to Branded drugs.

1. INTRODUCTION

A pharmaceutical company when invents or discovers a new moiety of drug after meticulous efforts of research and development and costly trials, takes a patent for that drug so that any other pharmaceutical group may not imitate the same molecule of drug. Such class of drugs is known as branded drugs and is sold in the market bearing a brand name of that drug.[1] The time duration of patent for a newly invented drug is around twenty years and till this time, the ownership of the same drug is entirely in the hands of manufacturer. No other body can copy or manufacture the same drug molecule. An additional focus is to be given on another class of drugs here, which are the generic drugs. These drugs are identical in composition of active ingredient/ingredients, strength, quality, purity and efficacy as the branded ones. Generic drugs can be manufactured only when the patent of a particular branded drug expires but an advantage which is to be appreciated here about the generic ones is that these are much cheaper to their branded counterparts as they do not need the extensive costs for researching, development and trials as done in the invention of any new drug.[2] The generic drugs stands nowhere less than the branded drugs considering their effectiveness and safety. Being much cheaper than their branded counterparts, this class of drugs have an additional advantage of ease in purchasing amongst every class of people. In some countries, where poverty is a major issue and a number of persons die because of untreated fatal diseases due to the inability of purchasing the costly branded drugs, these generic drugs act as a boon for them.

2. EFFECTIVENESS OF GENERIC DRUGS IN COMPARISON TO BRANDED DRUGS

For the generic drugs approval and coming into the market, bioequivalence studies have to be done on such type of drugs. The bioequivalence data of generic drug is compared with its branded counterpart and if both the data gets matched, then it gives a proof of the quality, therapeutic efficacy and safety of generic drugs. The bioequivalence studies involve the use of healthy volunteers in whichboth types of drug in similar amountsis administered via same route and then the pharmacokinetic parameters and bioavailability is studied and compared.[3-5]Sophisticated techniques like High performance liquid chromatography (HPLC), Gas chromatography(GC), Mass spectroscopy (MS) are being used to assess the plasma drug concentration of both types of drugs in order to find the pharmacokinetic parameters and bioequivalence data. FDA guidelines state that the generic drugs must be bioequivalent to its branded counterpart and only the generic version with proved bioequivalence and effectiveness are only given the approval to enter into the market[5].Generic drugs are meticulously tested to make certain their presentation and ingredients meet the FDA's standards for equivalency.[6]

Table 1:Comparison of cost between Generic and Branded drugs in India[10,11,12,13]

S. No.	Generic drug	Class of drug	Manufacturer	Market price (Rs)	Branded drug	Manufacturer	Market price(Rs)
1.	Aceclofenac Tablets IP 200 mg	NSAID	Edmund Healthcare Pvt Ltd,Chandigarh (Punjab)	10	Aceroc	Wockhardt	29.10 (10 Units)
2.	Acyclovir 400 mg Tablets	Anti-Viral	Vega Biotech Pvt Ltd,Vadodra (Gujrat)	31.6	Acivir DT	Cipla	60.99(5 Units)
3.	Metformin Hcl 1000 mg SR Tablets	Anti-Diabetic	Care Formlation Labs Pvt Ltd, New-Delhi	11.05	Geminor-M Forte	Macleods Pharmaceutical Ltd	60.50 (10 Units)
4.	Omeprazole 20 mg Capsules	Proton Pump Inhibitor	Schwitz Biotech,Ahmedabad	7	Acichek	Sanofi Aventis Pharma India	29.75 (10 Units)
5.	Folic Acid Tablets IP 5 mg	Anti-Anaemic	Alpha Pharmaceuticals, Faridabad(Haryana)	2.9	Folitab	Intas Pharmaceutical Ltd	30 (30 Units)
6.	Montelukast Sodium Tablets IP 5 mg	Antiasthmatic	Curelife Pharmaceuticals, Ambala (Haryana)	12	Singulair	MSD Pharmaceuticals Pvt Ltd	84 (7 Units)
7.	Lansoprazole 30 mg Capsules	Proton Pump Inhibitor	Actiza Pvt. Ltd,Surat,Gujrat	42	Lanzol-30	Cipla	54
8.	Alendronate Sodium 70 mg	Biphosphonates	Radix Pharmaceuticals,	94	Osteofos	Cipla	116 (4 Units)
9.	Cefuroxime Injection 750 mg	Antibacterial	Talent Healthcare,Ahmedabad (Gujrat)	64	Supacef Injection	GlaxoSmithkline	114
10.	Gabapentin Capsules USP 300 mg	Antiseizure	Dycott Healthcare,Baddi,DisttSolan(HP)	23	Gabator 300 mg	Torrent Pharmaceuticals Ltd	98.75
11.	Tenofovir Tablets 300 mg	Nucleotide reverse transcriptase inhibitor	Million Health Pharmaceuticals, Chennai	178	Tenvir-EM	Cipla	2000
12.	Vincristine Injection IP 1 mg	Anti-Cancerous	Lexicare Pharma Pvt. Ltd, Ankleshwar, Gujrat	25	Oncocristin-AQ	Sun Pharmaceuticals	52 (1 ml)
13.	Oxaliplatin Injection 50 mg	Anti-Cancerous	Revacure Lifesciences, New-Delhi	430	Dacotin	Dr Reddy's Laboratory Ltd	4,938
14.	Progesterone 200 mg SR Tablets	Progestins	Tissue Overseas, Surat, Gujrat	163	Algest	Cadila Pharmaceuticals Ltd	187
15.	Orlistat 120 mg Capsule	Lipase Inhibitors	Fortune Healthcare, Vadodara, Gujrat	130	Olisat	Biocon Ltd	380
16.	Temozolamide 100 mg Capsule	Anti-Cancerous	NetcoPharma,Telangna	1,330	Temolon	CelonLaboratories Ltd	9,200
17.	Leflunomide Tablet IP 20 mg	Anti-Arthritic	Taj Pharmaceuticals Ltd, Rajgad, Maharashtra	66.38	Arava	Sanofi Aventis Pharma Ltd	1,384
18.	Efavirenz Tablet IP 600 mg	Anti-Retroviral	Medchem International Ltd,Hyderabad	423	Odivir	Cipla	1,070

Thus from these stringent parameters and approval methodology of generic drugs, we could depict that generic drugs are fully effective as the branded ones.

3. HOW THE GENERIC AND BRANDED DRUGS WORK IN THE BODY

Various studies are done which have proved that generic drugs work in the same way in the body as the branded drugs. The FDA and other governing bodies have already mentioned in their protocol of approval that the generic drugs must have similar standards as the branded drugs. They should not be inferior in any aspect to their branded counterparts. Generic drugs are meticulously tested and inspected several times to meet the rigid standards of FDA.[7]Moreover, the FDA requires that a generic drug manufacturing plant meets the same high standards as a plant for a brand name drug. The FDA also conducts several inspections in this aspect to make highly sure that the manufacturing plant of generic drugs has similar standards as the branded manufacturing plants.[8] Thus it can be inferred that due to the similar required standards of both the category of drugs, the generic drugs work identically in the body and are equally bioequivalent.

4. COST EFFECTIVENESS OF GENERIC DRUGS IN COMPARISON TO BRANDED DRUGS

The generic drugs have an immense advantage of being much cheaper with no compromise on the quality and efficacy as compared to their branded counterparts. The utmost reason behind this is that these do not require the cost expenses on the research and development of the drug. The costly clinical trials are also not required to be repeated again which surely make these drugs cheaper. The cost on the advertising, marketing and promotion of these drugs is also lacking after manufacturing of generic drugs.[8] Some studies have reported that the replacement of generic drugs with branded drugs have resulted in a saving of 10 billions of dollars every year in US[9]. The data in the given table No.1. depicts the cost comparison between generic and branded drugs and could be used as a judgmental criteria to realize that how generic drugs are much cost effective than branded drugs.

5. REGULATIONS AND CONTROL OF GENERIC DRUGS

The prerequisite for the production of generic drugs is that these could be manufactured only when the period of patent of its branded counterpart is expired. For a new moiety, a New drug Application (NDA) is required but for generic versions, an Abbreviated New Drug Application (ANDA) is necessary which do not require the stringent standards as required by the NDA.[14]

The ANDA system was basically developed by the 1984 Drug Price Competition and Patent Term Restoration Act(Hatch-Waxman Act) in US and it is applicable for the approval of generic drug segment from 1962 onwards.[15] The significant regulatory requirements for generic drug is that it should contain the same active ingredient as the innovator drug. It should be similar in strength, dosage form and route of administration. It should be bioequivalent also.[16]

6. CONCLUSION

Generic drugs are a safe and effective form of medication and is a suitable option when compared to the branded drugs. These drugs are bioequivalent, safe and much cheaper than its branded counterparts, which makes them as a feasible form of medication. The government of developing countries are now focusing on the use of generics and much of emphasis is given to aware the general public about the rational use of generic drugs. The misconception about the use ofgenerics is now decreasing up to some extent from the minds of people regarding its safety, effectiveness and its competence.

REFERENCES

1. Davit BM, Nwakama PE, Buehler GJ, Conner DP, Haidar SH, Patel DT. Comparing generic and innovator drugs: A review of 12 y of bioequivalence data from the United States food and drug administration. Annals ofPharmacotherapy. 2009;43:1583-97.
2. Arafat Mosab, Ahmed Zahaa, Arafat Osama. Comparison between generic drugs and brand name drugs from bioequivalence andthermoequivalence prospective. InternationalJournal of Pharmacy and Pharmaceutical Sciences.2017; 9(6): 1-4.
3. FDA Fact sheet: What's involved in reviewing and approving generic drugs applications? Available from: https: www. fda. gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm506040 accessed on 10/12/19.
4. Moore N, Berdai D, Begaud B. Are generic drugs really inferior medicines? Clinical Pharmacology and Therapeutics.2010;88(4):302-304.
5. Wilner AN. Therapeutic equivalency of generic antiepileptic drugs: Results of a survey. Epilepsy and Behavior.2004;5(1): 995-998.
6. Qumbar M. DOE based stability indicating RP-HPLC method for determination of lacidipine in niosomal gel in rat: Pharmacokinetic Determination. PharmaceuticaAnalytica Acta.2014; 5:314-317.
7. Sanaa A. Awareness and perception of national pharmacovigilance center among lebanese medical staff. Journal ofPharmacovigilance. 2016;4(1):1-5.
8. https://www. verywellhealth. com/generic-drug-safety-and-effectiveness-1738890 accessed on 12/12/19.
9. Dentali F, Donadini MP, Clark N, Crowther MA, Garcia D, Hylek E. Brand name versus generic warfarin: A systematic review of the literature. Pharmacotherapy Journal.2011;31(3):86-93.

10. www. pradhanmantrijanaushdi. com accessed on 12/12/19.
11. www. medindia. netaccessed on 12/12/19.
12. www. indiamart. comaccessed on 12/12/19.
13. SingalGL,NandaArun,Kotwani Anita. A comparative evaluation of price and quality of some branded versus branded–generic medicines of the same manufacturer in India. Indian Journal Of Pharmacology.2011; 43(2):131-136.
14. Stegemann S, Klebovich I, Antal I, Blume HH, Magyar K, Nemeth G. Improved therapeutic entities derived from known generics as an unexplored source of innovative drug products. European Journal of Pharmaceutical Scinces.2011;44(2):447-454.
15. Moore N, Berdai D, Begaud B. Are generic drugs really inferior medicines? Clinical Pharmacology and Therapeutics.2010;88:302-304.
16. Swain Suryakanta, DeyAnkita, PatraChinamNiranjan, EswaraMuddana, RaoBhanoji.Pharmaceutical regulations for generic drug products in India and US. Case Studies and Future Prospectives.2015;3(2):1-6.