

Sketchy knowledge skeptical attitude towards generic and branded drugs

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Abstract

Objective: The aim of the study was to evaluate the medical student's knowledge and attitude towards generic drugs and categorize if a drug is generic or branded from the drug label.

Method: A prospective cross sectional survey was undertaken among 90 final year medical students. 17 item questionnaire was developed, validated and administered to assess their knowledge and attitude on generic vs. branded drugs.

Results: In our survey 71% students knew that generic drugs are bioequivalent to branded drugs but only 17.77% knew that generic are manufactured after expiry of patent. 73.33% students were aware that Medical Council of India has made generic prescription mandatory. 88% students were sensitive to the difference in generic vs. branded pricing. However 47% students felt that incentives will increase generic prescription. 50% of the students did not categorize the given sample of drugs either as branded or generic. 100% stressed the need of sensitization programmes at undergraduate level to update them on drug prescription patterns.

Conclusion: Good percentage of students had knowledge about generic medicines. They showed positive attitude towards generic prescription in their future practice and were ready to consume generic drugs themselves when required. In spite of this fact patients and practitioners still favour branded drugs.

Keywords: Generic drugs; Branded drugs; Prescription; Knowledge; Medical students

Introduction

A marketed drug has three names: chemical name, generic name, and brand name. A chemical name is a scientific name based on the compound's chemical structure and is almost never used to identify the drug in a clinical or marketing situation. The generic name commonly used to identify a drug during its useful clinical lifetime. The company that patents the drug creates the brand name (trademark). This name identifies the drug during the years that the company has exclusive rights to make, sell, and use it under patent law.

A brand name drug is the original innovator drug and has undergone rigorous tests and evaluation involved in developing the drug product. The innovator company has the sole right to manufacture and market the drug under a proprietary, trademark-protected name for a specified time *i.e.* for its patent duration. Generic version of a drug is manufactured by other companies for sale, after expiry of patent protecting innovator drug.⁽¹⁾ Generic Drug is defined as "A drug product that should have same active ingredient, strength, and dosage form, route of administration, quality, performance and intended use as the brand name drugs. They may differ in characteristics such as shape, release mechanism, labeling (to some extent), scoring and excipients (including colors, flavors and preservatives). This means it should necessarily be bioequivalent to branded drugs to obtain same therapeutic effect. It should meet the rigorous standards of good manufacturing practice (GMP) set by FDA."⁽²⁾

Generic drugs are marketed under the drugs approved International Non-proprietary Name (INN) with identified pharmaceutical substances or active pharmaceutical ingredients. The non-proprietary name is nowadays referred as the Generic name. Nowadays generic drugs are sold as a brand name as well as a non-proprietary name. These drugs may be called "ultragenics" or "pseudogenics"⁽³⁾ or Branded Generics. These generic versions have lower price because there is no need to repeat costly clinical trials, there is no advertising, marketing and promotion. When it comes to price, there is a big difference between generic and brand name drugs. On average, the cost of a generic drug is 80 to 85 percent lower than the brand name product.⁽⁴⁾

New drug development is a lengthy and costly process, so new drugs are granted patents as reward for the breakthrough of Innovator Company allowing them a period of exclusive marketing for a period of usually 20 years.⁽⁵⁾ The patenting system in India is governed by Patent Act 1970 and the latest amendment was implemented on April 2005. Under the Patents (Amendment) Act, 2005 patents will be granted both for products and processes for all the inventions in all fields of technology. The patent term will be twenty years from the date of the application under Article 33 of the Trade-Related Aspects of Intellectual Property Rights agreement (TRIPS) compared to the seven years under the 1970 Act, which is applicable to all the member countries and thus rules out all the differences in the protection terms prevailed in different countries.⁽⁶⁾ Once the patent expires, other companies

are permitted by law to manufacture the agent with different trade names or as generic drug without a trade name.⁽⁷⁾ In recent years government regulatory agencies have a strong tendency to encourage or even mandate the prescription and dispensation of drugs by generic names, with aim to control the costs. To facilitate the wider use of generic drugs, the FDA has published a list of all FDA approved drugs that is regarded as therapeutic equivalent.⁽⁸⁾ Many generic products are manufactured and distributed by the same company that marketed the original proprietary drug. India's pharmaceutical industry occupies a place of prominence globally and is ranked eighth. The Indian pharmaceuticals market increased from US\$ 6 billion in 2005 to US\$ 36.7 billion in 2016 and is expected to rise up to US\$ 55 billion by 2020. With a 72 per cent market share (in terms of revenue), generic drugs form the largest segment, 19% OTC and only 9% patented generic drugs account for 20 per cent of global exports in terms of volume, making India the largest supplier of generic medicines globally.⁽⁹⁾

National Pharmaceutical Pricing Authority (NPPA) is an organization of the Government of India, to fix/revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country, under the Drugs (Prices Control) Order, 1995 and undertake and/ or sponsor relevant studies in respect of pricing of drugs/ pharmaceuticals.⁽¹⁰⁾

The prescription written by the doctor has a significant impact on usage of generic medicines, particularly in developing countries where patients or relatives leave no stone unturned to buy exactly what is prescribed. Knowledge about generic drugs use in health facility is lacking in our country, though the government has passed a resolution for using maximum generic drugs at health facilities that is why we decided to conduct this study to assess knowledge and attitude of generic drugs and branded drugs among MBBS students with aim to sensitize them towards the importance of generic drug prescription.

Material and Methods

This study was conducted at a tertiary care teaching hospital and college Pt. JNM medical college, Raipur, Chhattisgarh (central India) among final year MBBS students in the month of July 2016. The institutional ethical committee of this college approved this study.

Study design: It was a prospective cross sectional questionnaire based study. Study participants consist of students of final year MBBS. A well-structured questionnaire was prepared based on previous studies.^(5,11) Part 1 of it included demographic details of participants. Part 2 was questionnaire consisted of 8 questions in knowledge section. To elicit attitude towards these drug 5 question were included in attitude section. 5 questions were related to their future practice towards these drugs. Last question 17 had 5 drugs for spot identification whether they were generic or branded. The responses for the items 1-11 were obtained in Five Point Likert scale, responses for the items 12-16 and were obtained in dichotomous manner. There was an open format question after 16 as to how they can identify generic from branded drug. The ethical permission for conducting the study was obtained.

Sample size: The questionnaire was given without any prior information to students. Those present on that particular day was our sample size. A total of 90 students responded.

Data collection: After explaining the nature and purpose of study, study subjects were interviewed by using structural questionnaire. Appropriate instructions were given about filling the questionnaire.

Statistical analysis: All data were analyzed with the statistical package for social science (version 23; SPSS).

Results

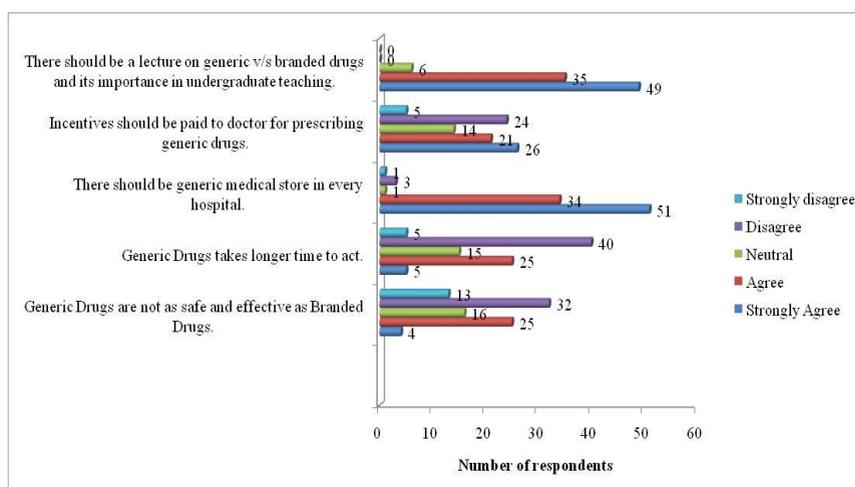
Demographic Characteristic: In our study, 48 boys and 42 girls participated with mean age, 22.5±2.5 years and all are medical students of 8th semester (final year MBBS).

Knowledge: Most students (71%) knew that generic drugs are bioequivalent to branded drugs and have same dosage form. 60% student strongly agreed to the fact that generic drug require GMP. 57.7% students didn't know that generic drug can be manufactured and marketed only after expiry of patent and 24.44% had no idea, and only 17.77% knew about patent. Most of them (73.32%) knew that as per MCI guidelines a prescriber has to prescribe generic drug preferentially and 18 students were neutral. 70% students were aware of generic drug stores run by government as Jan Aushadhi Stores and were helpful. Maximum (88%) students knew the difference in pricing also. (Table 1)

Table 1: Student's knowledge about generic and branded medicines

Variable	Strongly Agree	Agree	Neutral	Disagree	Strongly disagree
	n (%)	n (%)	n (%)	n (%)	n (%)
Generic Drugs are bioequivalent to Branded Drugs and Have same Dosage Form.	19 (21.11)	44 (48.88)	9 (10)	12 (13.33)	6 (6.66)
Branded Drugs are required to meet good manufacturing Practices.	19 (21.11)	35 (38.88)	18 (20)	15 (16.66)	3 (3.33)
Generic Drugs can be marketed only after expiry of patent.	10 (11.11)	6 (6.66)	22 (24.44)	34 (37.77)	18 (20)
MCI act (Prof. Conduct, etiquette and ethics) regulation 2002 states that every prescriber should as far as possible prescribe generic drugs.	22 (24.44)	44 (48.88)	18 (20)	5 (5.55)	1 (1.11)
Setting of 'Jan Aushadhi' generic drug store by government of India around the country is helpful.	28 (31.11)	35 (38.88)	27 (30)	0 (00)	0 (00)
There is huge difference between pricing of Generic Drugs and Branded Drugs and it has influence on overall health expenditure.	51 (56.66)	28 (31.11)	7 (7.77)	4 (4.44)	0 (00)

Attitude: Only 32.22% (29) students felt that generic drugs are inferior in safety efficacy and onset of action whereas 52.22% (47) students felt that it is not so and 16 were neutral. In spite of the above attitude almost all felt the need of generic drug store in every hospital. 52.22% (47) students even felt that need of incentive to prescribe generic drug. 100% stressed the need of early sensitization at UG level for prescribing and consuming generic drug (Fig. 1).

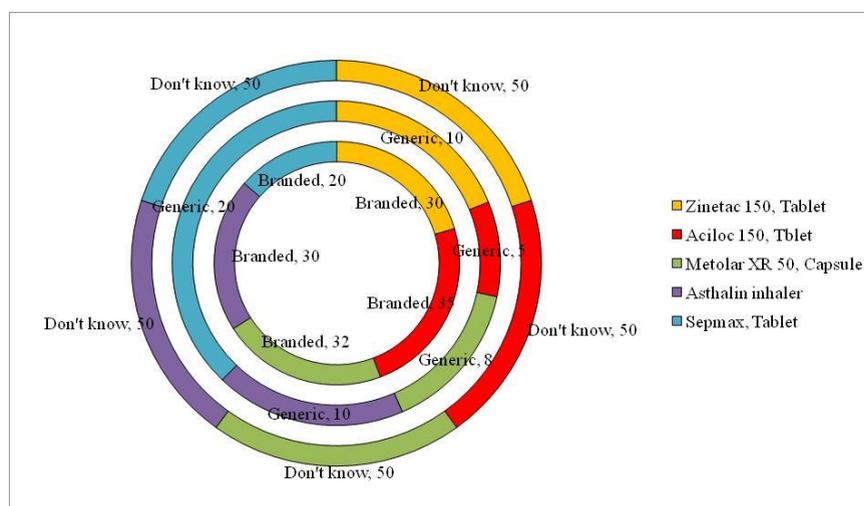
**Fig. 1: Attitude of students towards generic & branded drugs**

Practice: When asked about future practice pattern 77.7% students thought that they would prescribe generic drug while 22.2% respondents were doubtful that they will prescribe generic drugs. When required 70% students said they would consume generic drug for themselves also. Only 11.11% students had read some article regarding safety efficacy of generic drug. This shows that they feel this topic is not so important and relevant as they have not started prescribing. 91.11% (82) students were not aware about the website nppaindia.nic.in, where they can look for the price of the drug. 44.44% (40) student said they can identify the drug from its label if it is generic drug or branded but when asked to identify 5 different drugs, they could not categorize correctly and they had many misconceptions (Table 2).

Table 2: Student's view about future practice

Variable [n (%)]		Yes [n (%)]	No [n (%)]
1.	You will prefer prescribing generic drugs over branded drugs in future.	70(77.7)	20(22.2)
2.	Will you prefer taking Generic Drugs over Branded Drugs?	63(70)	27(30)
3.	Have you read any article regarding or comparing safety and efficacy of Generic Drugs v/s Branded Drugs.	10(11.1)	80(88.8)
4.	Are you aware about website nppaindia.nic.in	8(8.8)	82 (91.1)
5.	Can you identify if a drug is Generic or Branded by seeing its label	48(53.3)	42(46.6)
6.	If yes then how:	18 students answered this question- the different answers were- a) by the price of the drug if it is costly it is branded b) by the quality of packing –good packing means branded c) by the name of pharmaceutical manufacturer or distributor –Renowned company means branded d) if ® or ™ is written as superscript after the name of the drug then it is branded.	

Identification of drugs: 50 students did not know if the drug was branded or generic among all five drugs. Remaining of them identified the drugs as branded or generic, which were wrong interpretation (Fig. 2).

**Fig. 2: Identification of drugs**

Discussion

According to our study we have observed that most of the students (71%) were aware about generic drugs and branded drugs and knew they are bioequivalent, have same dosage form and require good manufacturing practice. This is similar to a study where large numbers of students (79.5%) were aware about the bioequivalence of generic drug and they need to follow good manufacturing practices.⁽⁵⁾ A study by Badwaik *et al.*, believed that generic medicines are inferior to branded drugs on efficacy (32.43%) and quality (28.83%) and 77.6% felt that such bioequivalence studies should be more vigorous.⁽¹²⁾

There are mixed reports about generic bioequivalence. After the loss of patent protection for bupropion [Wellbutrin (GlaxosmithKline)] many reports of loss of its antidepressant effect or new or

worsening adverse effects were submitted to US food and drug administration among patients who had switched from the brand name to generic version.⁽¹³⁾ Subsequently various generic version of bupropion were found not to be bioequivalent to brand name version of bupropion.⁽¹⁴⁾ On the contrary several evidence, has been found that generic drugs are as effective as their branded counterpart. A meta-analysis of 47 studies comparing effectiveness of 9 classes of cardiovascular medications found no evidence of inferiority of generic version including anticoagulant and antiarrhythmics.⁽¹⁵⁾ In India CDSCO ensures uniformity in quality, efficacy and safety of pharmaceutical products. It is mandatory for two drug products manufactured and marketed by different companies, containing same active ingredient(s) must undergo bioequivalent studies and must be

therapeutically equivalent and can be used interchangeably.⁽¹⁶⁾ Only 17.77% students knew that generic drugs can be marketed after expiry of patent which is very less compared to the study by Gupta S K *et al.* where 42% had knowledge about patent protection for branded drugs.⁽⁵⁾

Two third students (73.33%) knew about MCI guidelines for generic prescription and studies in other part of our countries showed similar results where 79.5% doctors were aware that Indian medical council act (professional conduct, etiquette and ethics) regulations 2002, states that drug with generic name should be prescribed by every physician. It also include that he/she shall ensure that there is a rational prescription and use of drugs.⁽¹⁷⁾ In a study students agreed that generic drug help in reducing overall health expenditure as they are cheaper but only 35.2% in their study knew about Jan Aushadhi generic drug stores in India⁽⁵⁾ whereas in our studies approx 70% students had the knowledge of these drug stores and they agreed over the fact that this price difference has major influence on health expenditure. India is one of the largest producers of generic drugs and supplier worldwide. These drugs are cheaper by 70-90% in our country, if the pharmacies sale without greed. But when a generic drug is granted approval for manufacturing, it has to follow and fulfill strict regulations as per GMP required by the regulatory body with respect to identity, quality, purity and potency. In a study on interns and postgraduates, 32% said that generic are inferior in efficacy and 28% believe they are inferior in quality.⁽²⁾ Whereas another study among prescribers, 68.5% agreed that they were not inferior to Branded Drugs and in same study 75% were of view that generic drug are as safe as innovator drugs, more over 64.4% doctors felt their efficacy and onset of action similar to branded drugs.⁽⁵⁾ In a study in Malaysia most General practitioners were aware about Bioequivalence and Good manufacturing practices. Studies felt that interaction with prescribers and representatives of pharmaceutical companies increase prescription of drugs manufactured by them which are at times more expensive and at no demonstrated advantage.⁽¹⁸⁾ Therefore it is important to educate the medical fraternity from the root level to deal ethically and judiciously while interacting with medical representatives.

In our study 52.22% students felt the need of incentives to prescribe generic drug. This is due to the mindset that the branded drug manufacturing companies give incentives for prescribing their brands through it is illegal and punishable by law. Other studies show that only 11.2% practitioners felt that lucrative gifts and incentives offered by pharmaceutical companies motivate them to prescribe their brands, and 43.2% says that generic drug prescribers should get incentives.⁽¹²⁾ MCI bans gifts, incentives, parties, foreign trips and legal actions can be taken.

All participants in our study stressed on lectures at UG level for sensitizing about generic drug prescription. Stress has been given to training programs to increase awareness about generic drug for doctors and patients.^(5,12) If the health insurance policies reimburse only generic drugs then automatically patient will ask the prescriber to write generic drug. However physicians in Malaysia, felt that they would prescribe generic drug to the patient of low socio-economic status as they are cheaper.⁽¹⁸⁾ In France also the prescribers were of same opinion,⁽¹⁹⁾ whereas in Jamaica generic drug were prescribed to patients with their illness in view of their financial burden.⁽²⁰⁾ Indians also felt that generic drugs are for poor patients.⁽¹²⁾ Generic drug prescription leads to more economic and affordable treatment.⁽¹³⁾

In a study 58.9% practitioners had not read any article comparing safety and efficacy of generic drug vs. branded drugs⁽⁵⁾ while in other study 74.4% practitioners has not read any article about generic drugs.⁽¹²⁾ In our study 89% medical students had never read any article regarding or comparing safety and efficacy of generic and branded drugs. This could be due to the fact that they are not buying medicines and have not started prescribing yet. Interactive forms of continuing medical education such as academic detailing are effective methods of changing prescription of generic drugs and physician's behavior.⁽²¹⁾ And this could promote prescription of generic drugs. This in-turn would have economic implications. Providing free sample of generic drugs, advertisement, and addition of vouchers that patient could use when switching to or initiating a generic drug and educating the patient about financial benefits on long term use of generic drugs will result in increase in generic drug prescription.⁽¹³⁾ Continuing medical education programmers (CMEs) for clinicians and interactive sessions with patients must stress that brand name medications are not necessarily more efficacious, but certainly are more costly.

We could not find any precise study which stressed the identification of generic drug and Branded Drugs from the labels. Some countries have defined the minimum size of characters in which the generic nonproprietary name must be printed under the trademark labeling and advertising. In several countries the generic name must appear prominently in type at least half the size of that used for the proprietary or brand-name. In some countries it has to appear larger than the trade-mark name. The protected brand name or trade mark, registered with the US patent office, under which a manufacturer markets a product is written with an initial capital letter and is often distinguished with a registered trade mark (®), where as in generic symbol of trademark is not included.⁽²²⁾ In India we could not get any information about labeling. However Ministry of health and family welfare has issued directions on 12 Oct 2012 under section 33 (P) of Drug & Cosmetic act

1940 to all states and union territory for compliance in respect to the following: grant/renewal of manufacturing licenses of drug formulations in proper generic names only. This means that all drugs manufactured in India are generic drugs or branded generic drugs. However the composition of the product shall mention the name of the active ingredient as well as its strengths.

The drugs surveyed for identification by us (1) Zinetac 150 mg Tablet, (2) Aciloc 150 tablet, (3) Metolar XR 50 mg capsule, (4) Asthalin inhaler, (5) Sepmax tablet.

In our survey two different stripes of ranitidine were shown to students. One was Zinetac 150 mg Tablet manufactured by GlaxoSmith Kline, the innovator company and ACILOC 150 mg manufactured by Magfam. Ranitidine hydrochloride salt, solid dosage form was given patent US4521431 on June 4, 1985 to Glaxo Inc.⁽²³⁾ Ranitidine was first prepared as AH19065 by John Bradshaw in the summer of 1977 in the Ware research laboratories of Allen & Hanburys Ltd, part of the Glaxo organization. Ranitidine was the world's biggest-selling prescription drug by 1987.⁽²⁴⁾

Capsule Metolar XR (50 mg) is manufactured and marketed by Cipla Ltd. The main active ingredient or salt in this drug is Metoprolol succinate. Metoprolol was first made in 1969. The drug was registered in United States in 1978 as Lopressor by Ciba.⁽²⁵⁾ The tartrate is an immediate-release formulation and the succinate is an extended-release formulation. Metoprolol succinate 50 mg extended release formulation was granted patent US5081154 A on 14 Jan 1992 to inventor, Aktiebolaget Hassle.⁽²⁶⁾

Asthalin Inhaler 100mcg 200 metered doses – containing Salbutamol sulphate IP equivalent to Salbutamol IP 100 mcg, suspended in propellant HFA 134a (haloalkane refrigerant with insignificant ozone depletion potential) is manufactured by Cipla. Metered dose inhaler for albuterol was granted patent US 6131566 A on 17 Oct 2000 to Glaxo Wellcome Inc.⁽²⁷⁾

Sepmax (400 mg/80 mg) manufactured by GlaxoSmithKline. Tablets comprising trimethoprim and a sulfamethoxazole were granted patent US-4209513 on 24 June 1980 to Burroughs Wellcome Co.⁽²⁸⁾ This means the patent must have expired in June 2000 as per patent rules.

We could not get any information about patent expiry or new patent given to any new formulation of the above drugs. Newer formulations containing the same active drugs have got new patents. Registered trade mark TM OR, ® was written on Zinetec 150, Sepmax, Metolar XR50. We could not differentiate if these drugs were manufactured as branded or generic, but after 2012 only generic manufacturing license is given in India.

Conclusion

India is a leading generic drugs manufacturer. Generic medicines have resulted in improved access of medicines to all socioeconomic groups but there is unpredictability about the quality, safety and efficacy. But the mindset that branded drugs are more efficacious than generic drugs skews the prescription and consumption. This signifies that training programs for practitioners, medical students as well as for the patients in India is the need of the hour. Suitable substitution policy that gives pharmacists more freedom to switch to dispensing generic products will promote use of generic drugs. Regulatory authorities must lay down guidelines about Label on the drugs which can specify if it is branded or generic so as to pass the economic benefit to the patients so that they insist on generic prescription.

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Conflict of interest

There is no conflict of interest among the authors.

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