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Generic vs. Branded Drugs —A Market Survey



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HUMAN

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ABSTRACT

A generic drug is a chemically equivalent, lower-cost version of a brand name drug, costing 30-80% less. A brand-name drug and its generic version must have the same active ingredient, dosage, safety, strength, usage directions, quality, performance and intended use. In 2008, the average price of a branded drug was \$137.90, while the average generic prescription costs \$35.22. When a company develops a new drug and submits it for FDA approval, a 20-year patent is issued, preventing other companies from selling the drug during the life of the patent. As a drug patent nears expiration, any drug manufacturer can apply to the FDA to sell its generic version. Because these manufacturers did not have the same development costs (such as years of expensive research), they can sell the drug at a discount. Once generics are allowed, the competition keeps the price down. Today, almost half of all prescriptions are filled with generics. Generic drugs are thoroughly tested to make sure their performance and ingredients meet the FDA's standards for equivalency. A survey was conducted amongst three categories of population's viz Science background, Non-Science background and Pharmacists. A questionnaire was prepared with a fixed number of questions and data was collected from all the population, Statistics was applied and the inference drawn based on the results of the analysis. The results of the survey show that variable percentage of the population knows about the effectiveness of the generic drugs. Only 43 % of the science background population agree that the same FDA guidelines are followed for generic drugs as for branded drugs. Thus, if a common consensus can be made by doctor's and pharmacist, the most effective drug can be made available at the best price.

INTRODUCTION

Repeatedly the importance of generic prescribing has been emphasized, primarily to reduce the cost of drugs. There are two concepts to be understood here, one is generic vs. patented drugs and the other is a drug's "brand name" vs. "non-proprietary name" or "generic name." The non-proprietary name is the name for the active ingredient in the medicine that is decided by an expert committee and is understood internationally (XI). Thus, paracetamol/acetaminophen is the non-proprietary name (generic name) while Crocin/Metacin/Meftal/Tylenol etc. are brand names. Generic drugs are the most preferred drug prescription given to patients in need of healthcare. Standard drugs are defined as drug products that are comparable to a brand/ reference listed drug product in dosage form, strength, quality and performance characteristics, and intended use. Non-name brand drugs have a cheaper price that affects the client's choice of drug. These drugs are cheaper because the company that distributes them does not have to go through all the marketing to get this drug popular. The generic drug is a copy of the brand drug whose patent expires ten years after it is released to clients. Name brand drugs are drugs made by the industries that are usually advertised and are more expensive than generic brands. Brand name industries state that the generic version of their drug is not safe and is less effective. It is a well-known fact that generic drugs are "drugs that are usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights" (XII). When it is said that doctors should prescribe generic drugs, it means that they should prescribe drugs manufactured by other companies after the expiry of the patent of parent drug of the innovator company. Very often, generic prescribing is misconceived as prescribed by a drug's generic name or non-proprietary name. All generic drugs have a brand name as well as a non-proprietary name but not all drugs having a non-proprietary name (generic name) may be generic drugs.

Drug corporations should submit abbreviated new drug application (ANDA) [V], for approval to promote a generic product. Drug corporations gained bigger access to the marketplace for pharmaceuticals, and originator corporations gained restoration of a patent lifetime of their product lost throughout FDA's approval method [VI-VIII].

The patent protects the investment within the drug's development by giving the corporate the only right to sell the drug whereas the patent is in the result. Once patents or alternate periods

of exclusivity expire, makers will apply to the authority to sell generic versions. The ANDA [III], method does not need the drug sponsor to repeat expensive animal and clinical analysis on ingredients or indefinite quantity forms already approved for safety and effectiveness

Similarities between generics and branded medicines

There is a common misperception that generic drug concentrations can be 80% to 125% of the brand name formulation; in other words that the variance may be up to 45%. This is not true.

1. One of the key parameters for bioequivalence is the area under the curve (AUC). The AUC is a mathematical calculation based on a graph of blood concentration versus time, and it correlates well with total drug exposure.
2. The AUC of a generic formulation must be no less than 80% or no more than 125% of the brand name formulation. There is an international consensus that differences within this range are not clinically significant.
3. More importantly, the 90% confidence interval of the AUC must also fall within 80% to 125%. Recall that the confidence interval is a range of measurements within which we can be confident that the true result lies. Therefore, for the entire confidence interval to fall within the 80% to 125% range, the variance is generally less than 5%. [X]
4. If Generic medicine is bioequivalent, it will presume that it can produce the same therapeutic effect as same as branded drugs. This means that new clinical studies are not needed for generic drugs.

Brand name companies sometimes manufacture generic drugs. These drugs may be called "ultra-generic" or "pseudo-generics."

Difference between generics and branded medicines

The possible differences are-

1. Excipients (inactive ingredients) may differ.
2. The product may also be slightly different in color, shape, or markings.

3. The biggest difference is cost. Generic drugs are generally less expensive than brand name comparators.

METHODOLOGY FOR SURVEY

The study was conducted for following target populations. The population chosen for study comprises of the following categories:-

Sr. No.	CATEGORY	NUMBERS CONSULTED
1.	SCIENCE BACKGROUND	40
2.	NON-SCIENCE BACKGROUND	40
3.	PHARMACISTS	40

Questionnaire for Science background population:-

GENERIC VS BRANDED DRUGS- A MARKET SURVEY

DATE-

BACKGROUND- SCIENCE

NAME-

LOCATION-



QUESTIONNAIRE

1. Did the Government of India have passed a law and rules about the generic medicine?

YES-

NO-

2. Is there any price difference between branded and generic medicine?

YES-

NO-

3. Had any person, doctor, pharmacist suggested you switch from branded to generic medicine?

YES-

NO-

4. What do you think about the reason behind high price of branded drugs?

Because of their brand value- Don't know-

5. FDA Guidelines followed by generic medicines are same as that of branded medicine?

YES- NO-

Questionnaire for Non-Science Background population:-

GENERICS VS BRANDED DRUGS- A MARKET SURVEY

DATE-

NAME-

BACKGROUND- NON-SCIENCE

AGE- **SEX-** **IF ANY ALIMENT DIAGNOSED-**

LOCATION-

QUESTIONNAIRE

1. Do you know about the generic medicine?

YES- NO-

2. Are generic medicines as safe as branded medicine?

YES- NO-

3. For selecting your medication, do you follow TV Ads?

YES- NO-

4. From where you heard or seen about any information regarding generic Drugs?

Newspaper- Hoardings- Television- Pharmacist-

5. The drug generally prescribed by your physician is?

Costly- Cheap-

6. The prescribed medicine generally is available at any medical store?

YES-

NO-

7. Does your doctor allows substitute in a case of non-availability of the prescribed medicine brand

YES-

NO-

Questionnaire for Pharmacists:-

GENERICS VS BRANDED DRUGS- A MARKET SURVEY

DATE-

BACKGROUND- PHARMACIST

NAME-

LOCATION-

QUESTIONNAIRE

1. Generic medicine/medicines are available in your pharmacy?

YES-

NO-

2. Is there any issue related to the availability of generic medicines?

YES-

NO-

3. Do you promote the sale of generic medicines?

YES-

NO-

4. Which pharmaceuticals company you know that makes generics medicine?

Ans-

5. Do you personally buy the generic medicine instead of brand?

YES-

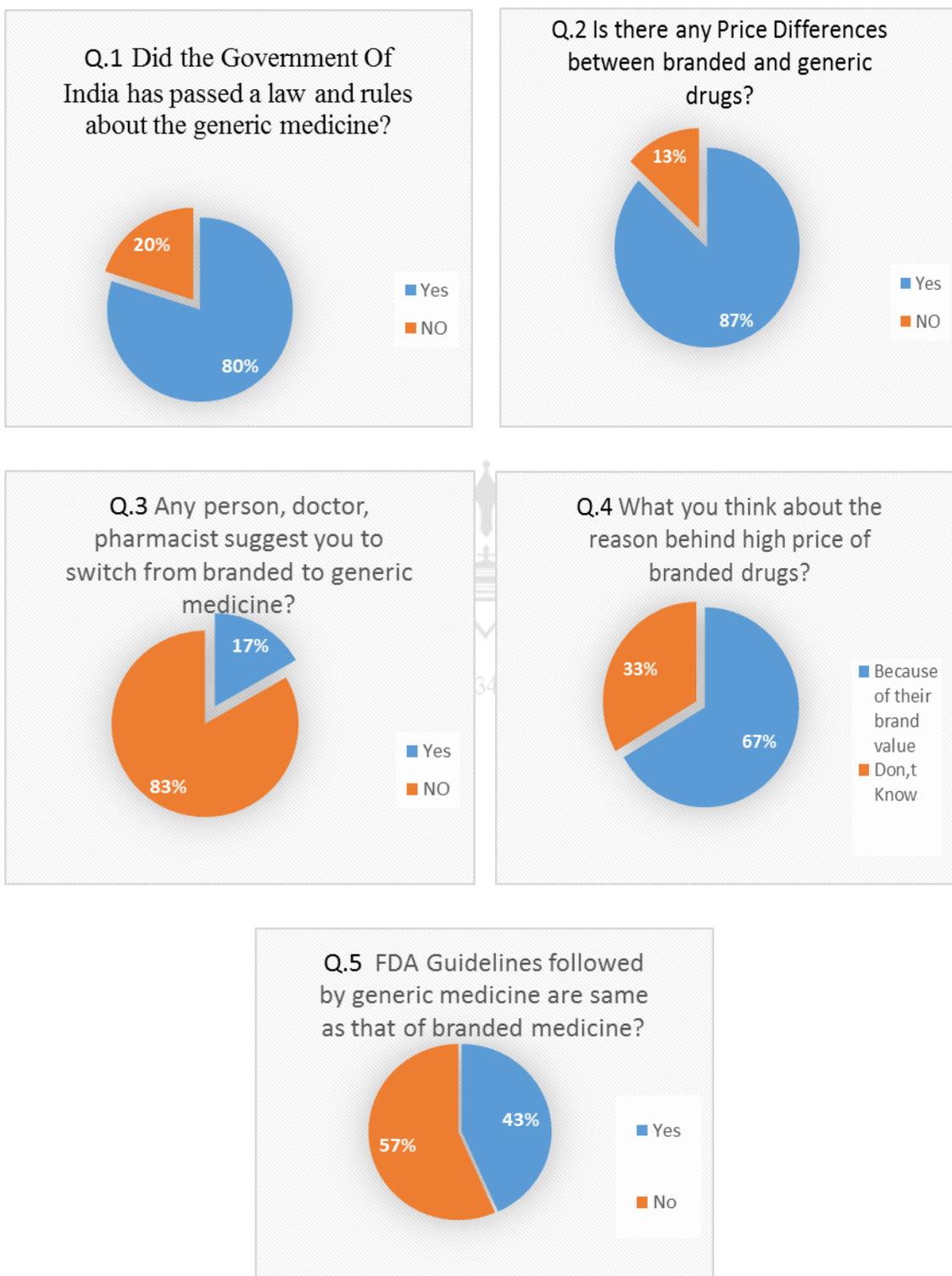
NO-

6. What is the percentage of generic medicines being prescribed by doctors?

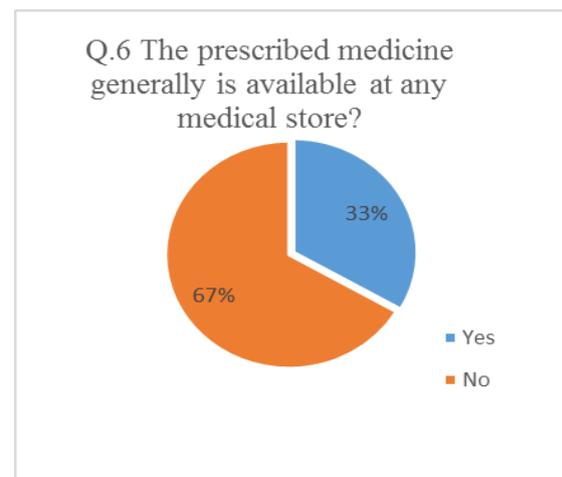
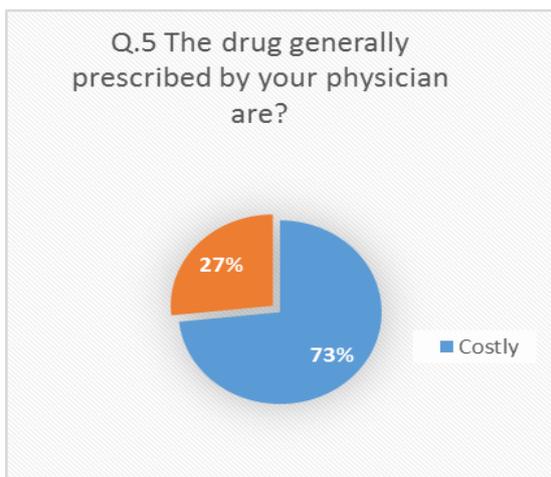
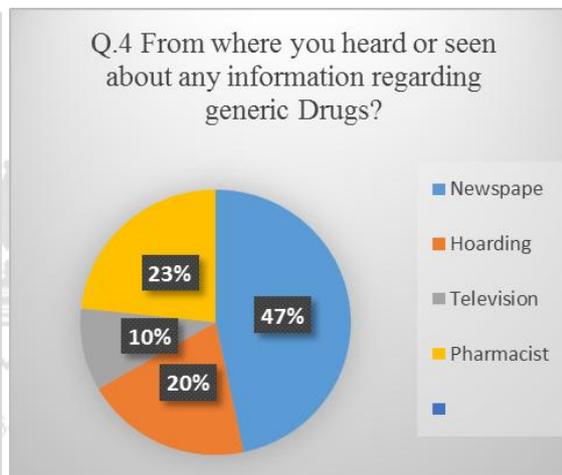
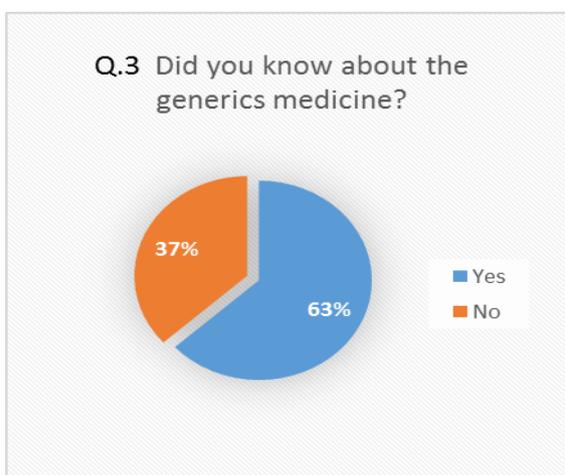
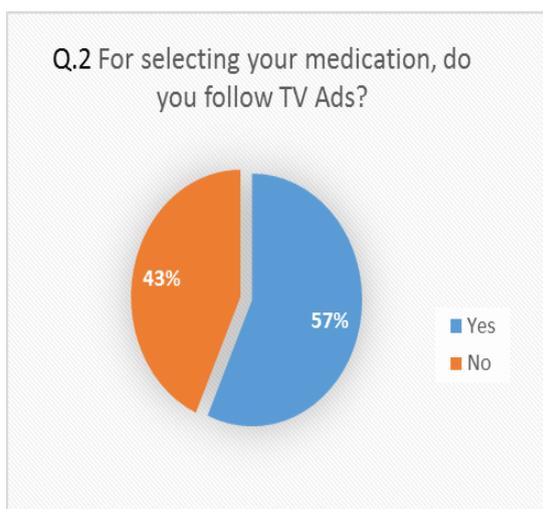
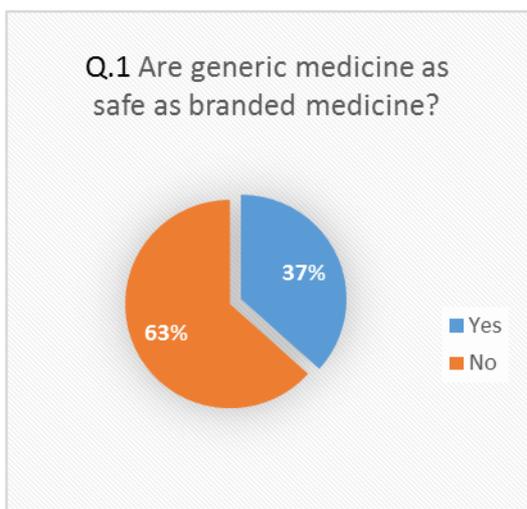
25%- 50%- 75%- 100%-

RESULTS

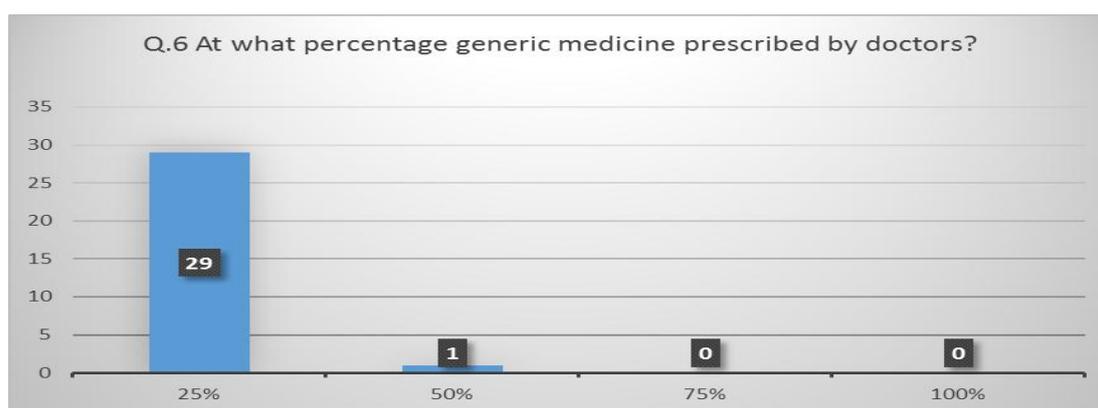
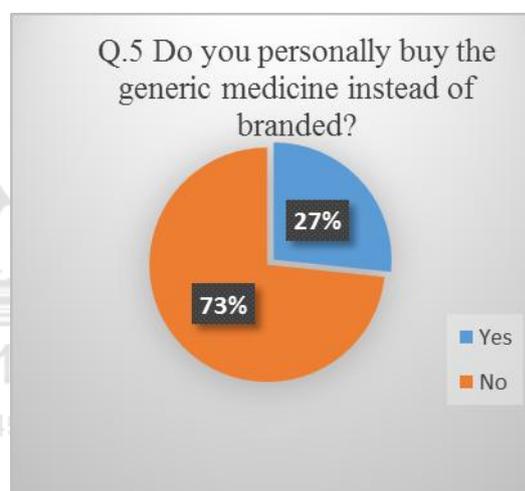
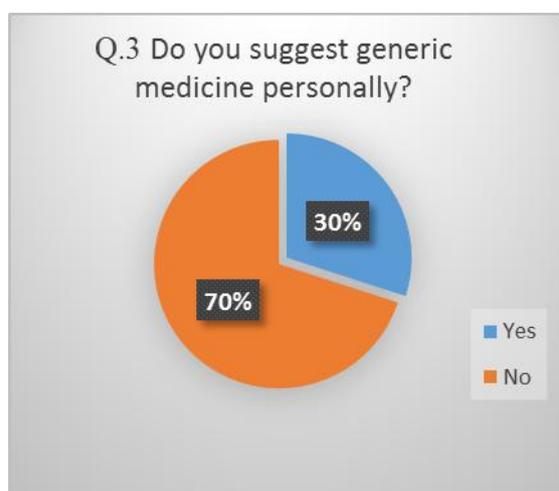
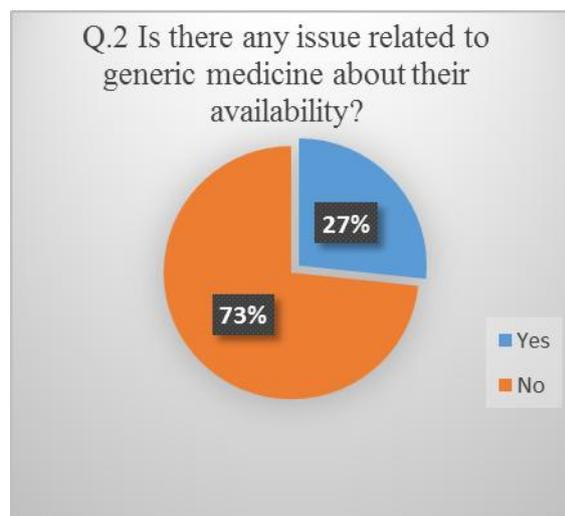
SCIENCE POPULATION SURVEY GRAPH



NON-SCIENCE POPULATION SURVEY GRAPH



PHARMACIST SURVEY GRAPH



CONCLUSION OF THE SURVEY

[A] SCIENCE BACKGROUND POPULATION demonstrated that individuals are very mindful of different government approaches to generics medications.

1. Almost 80% of people said that the generics are as effective as branded medicines.
2. Over 86% people found huge cost differences between generics and branded medicines.
3. Over 67% people were of the opinion that branded drugs price are hiked because of their brand value.
4. Over 19% said their doctors never discuss in terms of price difference between generics variant of branded drugs

Thus, it reflects that the science background population is well aware of the generics and branded drugs. They are also ready to switch over to the generic medications if their doctors prescribe such drugs.

[B] PHARMACISTS POPULATION

1. Only 67% of Pharmacists said that they keep few generics drugs. The only reason for not keeping generics drugs was due to lesser demand from the patients.
2. Over 30% Pharmacists never suggested generics medications to patients.

[C] NON SCIENCE POPULATION

1. Over 38% of people did not know about impacts of generics drugs.
2. Over 73% people said that the prescribed medicines are very costly.
3. Over 34% people were of the view that the medicines prescribed by the doctors are not available at every pharmacy store.
4. Over 14% people were of the view that the OTC (Over the Counter) and generics medicines are same.

Health care costs continue to rise. Therefore, consumers, providers, and policymakers need to assess the best way to keep health care affordable. Without adversely affecting access to quality care, with prescription drug (branded drug) costs serving as a major contributor to cost escalations, generic drugs offer an important tool for reducing the rate of growth in overall health expenditure. As more and more patents expire, the generic portion of the pharmaceutical market is expected to continue for increased sales. While brand-name drugs

certainly play an important role in medicine, generic drugs are a cost-effective alternative. Pharmaceutical costs are increasing faster than any other portion of the health care expense. Not only are generic drugs cost-effective, but also they are safe. Generic drugs are bioequivalent to their brand name twins. As generics tend to be older, they are generally less risky than new drug therapies. Generic drugs offer sound treatment options for patients. So patients should be told about the generic drugs and myths should be solved that "costlier will be effective." Thus, if a common consensus can be made by doctor's and Pharmacist, the most effective drug can be made available at the best price.

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