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Comparative Analysis of Generic Drugs Over Proprietary Counterparts In Indian Market

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Abstract

Drugs are any substance either biological or chemical and when consumed affects the physiological function of the body. These drugs are classified as OTC drugs or Prescription drugs. Both OTC drugs and Prescription drugs are available as Generic drugs or Branded/Proprietary drugs. While Branded drugs are protected by a patent for a particular number of years, generic drugs are not. Generic drugs only have to meet the same bio-equivalence requirement as their branded counterparts. Also, Branded drugs take a lot of time to get approved while generic drugs take a much lesser time. Due to the time taken for the Branded drugs to get approved, the costs used in the development of the drug, branded drugs then to get very expensive in the market while generic drugs are cheaper.

Keywords: Generic; Branded; Proprietary; Bio-equivalence; Drugs; Costs

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Introduction

Drugs are any substance (biological or chemical) except food that when consumed affects the physiological function of the body. It can also be defined as substance used in the treatment, cure, mitigation, diagnosis and prevention of diseases [1]. These drugs can be classified as:

- · Prescription drugs
- Over the Counter drugs

Prescription Drugs are drugs prescribed by a doctor, usually purchased at a pharmacy

and prescribed for only one person and to be used only for that one person. Some examples of prescription drugs includes Abacavir, Athralin, Quinapril, etc.

Over the Counter Drugs are also called Non-Prescription drugs are drugs that are usually sold over the counter without a doctor's prescription. Over the counter drugs can be analgesics, NSAIDs, decongestants, antacids, anti-fungal drugs, cough suppressants (e.g anti-tussives and expectorants), anti-acne drugs, some topical antibiotics (usually available in the form of creams, ointments, powder, sprays, etc.) [2].

Characteristics of Otc Drugs

- The benefits of OTC drugs outweigh the risks of the drug.
- The chances of misuse and abuse are lower.

- They can be easily used for self-diagnosed health conditions.
- The need of a health professional for safe and effective use is not required.
- OTC drugs are usually regulated by Active Pharmaceutical Ingredients (APIs) that are safe and effective when used without a doctor's advice.

Both Prescription drugs and Generic drugs can be sold as either Generic Drugs or Proprietary Drugs [3].

Generic Drugs

Generic drugs refer to the chemical composition of a drug and not the innovator drug which has a brand name in which the chemical composition of the drug is sold as. It is usually identical as a proprietary drug in dose, potency, route of administration, quality, its action and does the same the work the drug was manufactured for. The term 'generic' when used to describe household items implies that the item is cheaper and can be less effective and a duplicate version of a brand name product [4]. But in the case of generic drugs, they are of the same quality and are as effective as that of the branded counterpart. The generic name is the name for the active pharmaceutical ingredient that is responsible for the therapeutic action and is found in the medicine that has been made.

In other words, the generic name of a drug is the official name of a drug. It contains Active Pharmaceutical Ingredients same as the original brand name formulation.

Generic drugs are labelled with the manufacturer's name and generic non-proprietary name. The generic name of most generic drugs are usually a shortened version of the drug's chemical name, structure or a formula. Generic drugs have to be same and be within an accepted bio-equivalent range of their branded counterparts as their pharmaco-kinetic and pharmaco-dynamic properties.

Generic drugs usually become available after the patent protection to the original developer of a drug expires. Generic drugs may contain different Inactive Pharmaceutical ingredients such as demulcents, suspending agents, etc. that do not disturb the body to cure illnesses and may be different in physical appearance and shape. Yearly, about \$10 billion is saved at drug stores and his is because generic drugs are purchased, and when hospitals use generic drugs in the treatment of drugs more is saved [5].

What requirements do generic drugs have to meet?

Generic drugs must meet all of the same requirement of the same requirement of their branded counterparts. They must

- Have the same active pharmaceutical ingredients.
- Have the same dosage form (oral, topical, intravenous etc.)
- · Have the same strength and purity.
- · Have the same conditions of use.
- Possess the same action and dissolving rate as the proprietary counterpart.
- Be manufactured according to strict standards set by the Food and Drugs Administration's (FDA's) Good Manufacturing Practices for the proprietary counterparts [6].

Proprietary/Branded Drugs

Proprietary drug is a drug that has a trade name and is protected by a patent (means that a drug can be manufactured and sold by the innovator company). A patent is given because pharmaceutical organisation spends lots of money and resources to make, develop and discover a new drug substance and hence they are given the exclusive rights to make and dispense the medicine for a particular duration. At the time of the patent protection, only the innovator company can make the drug and this is the reason a lot of people trust and know the proprietary drugs [7].

How proprietary drugs are approved

Approval of a drug takes a long process. A drug often times developed to treat a particular disease may be discovered by chance to have other uses. Example, In the 1960s Retrovir (Zidovudine, also known as AZT). This drug was studied as an

anti-cancer drug with disappointing results. Few years later, the same drug was found to be useful in the treatment of Acquired Immunodeficiency syndrome. The drug was approved by the FDA for Glaxo Smith Kline [8].

The drugs are usually taken to Food and Drug Administration to be reviewed. Sometimes the drugs taken to the FDA that have undergone testing on animals may not be allowed for human testing. The FDA scrutinizes the designs of clinical trials, to the manufacturing conditions to the severity of the side effects [9].

Evaluation and Approval Procedures

The FDA (U.S), the authority responsible for the evaluation of drugs approves a generic drug if the studies that have been conducted shows that both the proprietary drug and generic counterpart are bio-equivalent. The authority also ensures that the generic counterpart has the same/right amount of Active Pharmaceutical Ingredients and was manufactured according to the Good Manufacturing Practices requirements and must differ from its proprietary counterparts in size, colour and shape [10].

Stages of drug development and review

- The innovator drug company sends an Investigational New Drug Application.
- The testing findings conducted on the animals used in the laboratory and what they assert the drug can to do on humans must be shown by the organisation i.e sponsors, companies, research institutions, etc. [11,12].
- The FDA decides if it is safe to proceed with the testing in humans.
- After the Investigational New Drug Application (IND) has been investigated and reviewed by the FDA and by a local Institutional Review Board the drug can be approved for human testings.

For the human testings, phases are divided into following phases:

- **1. Phase I:** This is done to know the drug's side effect and usually about 20 to 80 persons are used for the testing.
- 2. Phase II: Phase II starts when there is no unacceptable toxicity. In phase I, the study emphasized on safety, the phase II is about effectiveness. The object of this phase is to gather basic data on if the drug works in people who are having a particular illness. It takes about 300-400 patients for the study in this phase.
- **3. Phase III:** Phase III studies only occur if there is an evidence of evidence is shown in phase II. More safety and effectiveness information are gathered. Usually about 500-3000 patients are used.
- Then the pre-NDA (New Drug Application) period.
- For the FDA to grant a drug for marketing recommendation, the innovators sends a New Drug Application to the FDA.
- Upon receiving the New Drug Application (NDA) the authorities agree to record the application so it can be examined.

- When the New Drug Application (NDA) is recorded, a Food and Drug Administration (FDA) review team rates the innovator's research on the drug's safety and performance. The FDA team consists of medical doctors, microbiologists e.t.c.
- The information that is given as the label is scrutinized and rated by the FDA.
- The manufacturing site as well as the equipment and facilities to be used for production and manufacturing is inspected.
- For a drug to get approved it must be considered safe. The dangers of the drug is less than the benefits of the drug. The drug is considered safe.

The study results gets scrutinized by the review team and they look for available issue with the application. A written assessment having conclusions and proposal about the application is written by each reviewer. Then team leaders, office directors and division directors consider the evaluations made by the reviewers. In few cases, an accelerated approval is given to some drugs for serious life threatening illnesses that lack good treatments. This allows a New Drug Application (NDA) to be being reviewed by the authorities. Gleevec (Imatinib mesylate) received accelerated approval. It is a drug taken through the mouth, used on patients with a life threatening form of cancer called Chronic Myeloid Leukemia (CML). Gleevac blocks enzymes that plays a growth in the growth of cancer cells and the permission to use the drug was due to the results of a large phase II studies that showed that the drug could lessen the level of cancerous cells in the bone marrow [13].

How a proprietary drug becomes generic?

When a new drug is produced and marketed, it is protected by a patent for a particular period of time. At the expiry of the patent protected time, any other company can manufacture and sell the drug as long as it has the same Active Pharmaceutical Ingredient as the proprietary counterpart and the costs are usually lower since the company manufacturing the generic counterpart of the branded drug didn't incur the costs of original research, testing or marketing. Bioequivalence studies are usually done to for a generic drug to ensure that the bioequivalence is same with the branded counterpart. The generic drug gets approved on this basis [14].

Bio-Equivalence

When two drugs are similar it means that they have the physiological action on the patient. Bio-equivalence applies to pharmaceutically equivalent drug products in which the rate of bioavailability of the Active Pharmaceutical Ingredients are almost same under suitable and appropriate test conditions to achieve peak blood concentrations. Bio-equivalence is usually tested via *in vivo* testing in humans. It is done to determine the bioavailability parameters of a branded drug or the dosage form is same as the generic drug. Bioavailability is defined as the rate and extent of absorption of a drug from dosage form as determined by its concentration time curve or by its excretion

and urine. Bio-equivalence testing must be done through *in vivo* testing on humans as bioequivalence cannot be determined through testing done via *in vivo* testing in animals and *in vitro* testing. This bioequivalence testing is usually done on humans using established measures of bioavailability [15].

The measure of bioavailability includes

- **1.** Area under the curve (AUC) which refers to the concentration in blood over time t=0 to t=infinity.
- **2.** Cmax which refers to the maximum concentration of the drug in the blood.
- 3. Tmax which refers to the time taken for a drug to reach Cmax.

Also the same sample animal must be tested for bioequivalence in the species of the animal the intended drug is to be used. Studies are conducted by the manufacturers to determine if their generic version is bio-equivalent to the proprietary drug that is the generic drug releases its active ingredients (the drug) into the blood stream at the same time and amount as the proprietary drug. Bio-equivalence studies show that the generic drugs produces the same levels of drug in the blood at the same period of time and usually require about 24 to 36 volunteers. Bioequivalence studies are usually conducted on all types of drug dosage forms as long as they are available in the branded form. Bio-equivalence studies are also conducted on the brand name drug by the manufacturer before it can be approved and sold as well as the new form of an approved branded drug. The new form may be a modification of a drug either for patient acceptability or new strength of the same drug. Relative bioavailability is a measure used to determine bioequivalence between two drug product, thus, a manufacturer must show that 90% confidence interval (confidence interval is a kind of interval estimate and is used to show the amount of uncertainty associated with a sample estimate of a population parameter. It measures the probability that a population parameter will be between two set values. Usually confidence intervals are between 95% -99% but can be below that) for the ratio of the generic drug mean responses to that of the proprietary drug is within the limits of 80% to 125%. These studies are conducted to show how well a generic drug works in comparison to its branded counterpart.

Comparative Analysis of Generic Drugs Over the Proprietary Counterpart on the Basis of How They Where Developed

Generic drugs can be compared with their proprietary on the basis on how they were developed. They include:

- Generic drugs takes lesser time to get approved while Proprietary drugs take a lot of time to get approved. It takes about a year for generic drugs to get approved while it takes about 10-15 years for proprietary drugs to get approved.
- **2.** Generic drugs do not incur lots of costs as the manufacturer only performs a bio-equivalence testing on

- the drug to ensure that it is has the same bioequivalence as its branded counterpart. While the branded drug undergoes lots of costs during the preclinical phase, the clinical phase, in marketing and transportation.
- **3.** Although the Active Pharmaceutical Ingredient is same for both generic and branded drugs, the Inactive Pharmaceutical Ingredient in generic drug is always different from the Inactive Pharmaceutical Ingredient in branded drugs [16].

Advantages of generic drugs over proprietary ones

The Major advantage of generic medication is the

- 1. Cost Benefits: Generic drugs can't be marketed at a price higher than the proprietary ones. This low priced drug makes it financially easier for patients to strictly adhere to a dosage schedule as high priced drugs may make it difficult for the patients completing the medication throughout the whole duration of the treatment. Generic drugs are cheaper because the company manufacturing the generic drug did not incur the costs of the original research, testing or marketing and thus cost is lower.
- BioEquivalent: Generic drugs meet strict guidelines and thus have the same amount of Active Pharmaceutical Ingredients delivered to the body at the same times as the branded product.

Disadvantages of generic drugs over proprietary counterparts

- **1. Contamination:** Generic drugs are sometimes produced in factories with cheap labour, improper storage conditions and with the wrong GMPs (Good Manufacturing Practices).
- 2. Consumer Confusion: A medicine having different name and appearance but is "the same" might end up confusing the patients. This means both the generic names and proprietary names must be unique to prevent a particular drug from being mistaken for another during prescribing and dispensing.
- 3. Reactions: Although generic drugs have the same Active Pharmaceutical Ingredients, the Inactive Pharmaceutical Ingredients are usually different and can affect the rate of absorption. The Inactive Pharmaceutical Ingredients turn a chemical into an acceptable drug product. Inactive ingredients are not harmful and they don't affect the body but sometimes these ingredients can cause severe allergic reactions in a few people and that is the reason branded drugs may be more preferred to another. Example: Bisulfites (e.g Sodium metabisulfites), usually used as a preservative in many products has been seen to cause asthmatic allergic reactions [17].

Advantages of proprietary drugs over generic drugs

1. They are patent drugs which means that they are the

latest drug in their class and may have newly discovered ingredient and benefits.

2. They have a well labelled container and are accurate [18].

Disadvantages of proprietary drugs over generic drugs

1. The only disadvantage of proprietary drugs is the high cost. Proprietary drugs are more expensive because we buy the drug, we pay for the research cost, costs used in proving it is safe, the costs for it to be marketed and transported. These costs makes the drugs very expensive to buy. This will be seen in the cost estimate of generic drugs and their branded counterparts.

Since both Generic drugs and Proprietary drugs are same in terms of active pharmaceutical ingredient, the same administration type, same dosage, same strength, the same condition of use, same purity, gets absorbed into the bloodstream at the same rate and same period of time as the branded counterparts, the comparison of both Generic drugs and its branded counterparts will be based on the costs.

Comparative Analysis of Generic Drugs Over Proprietary Drugs on the Basis of their Costs

1. Drug Name

Aminophylline 100 mg

Dosage type: Tablet

Quantity: 10 Tablets

Price (in Rs): 0.93

Branded Counterparts

Manufacturer: Shalina Laboratories Ltd.

Branded name: Aminophylline 100 mg

Dosage type: Tablet
Quantity: 10 tablets

Price (in Rs): 1.00

• Manufacturer: Densa Pharmaceutical Pvt. Ltd.

Branded Name: Aminophylline 100 mg

Dosage type: Tablet
Quantity: 10 tablets

Price (in Rs): 1.60

2. Drug Name

Amodiaquine 200 mg

Dosage type: Tablet
Quantity: 10 tablet

Price (in Rs): 4.62

Branded Counterpart

• Manufacturer: Parke-Davis (India) Ltd.

Branded Name: Camoquin 200 mg

Dosage type: Tablet
Quantity: 10 Tablets
Price in Rs: 5.00

3. Drug Name

Analgin 500 mg

Dosage type: Tablet Quantity: 10 Tablets Price (in Rs): 8.27

Branded Counterpart

• Manufacturer: Sun Pharmaceutical Industries Ltd.

Branded Name: Metnimez 500 mg

Quantity: 10 Tablets
Price (in Rs): 25.00

4. Drug Name

Aspirin 500 mg

Dosage Type: Tablets Quantity: 30 Tablets Price (in Rs): 8.53

Branded Counterparts

• Manufacturer: Shalina Laboratories Ltd.

Branded Name: Aspririn 500 mg

Dosage Type: Tablet Price (in Rs): 12.00

• Manufactuer: Natco Pharma Ltd.

Branded Name: Cotaspirin 500 mg

Quantity: 30 Tablets
Price (in Rs): 14.99

5. Drug Name

Becampicillin 400 mg Dosage Type: Tablet Quantity: 2 tablets

Price (in Rs): 10.62

Branded Counterparts

• Manufacturer: Astra Zeneca Pharma India Ltd.

Branded Name: Penglobe 400 mg

Dosage Type: Tablet

Quantity: 2 tablets Price (in Rs): 27.56

6. Drug Name

Verapamil 120 mg Dosage Type: Tablet Quantity: 10 tablets Price(in Rs): 19.64

Branded Counterparts

Manufacturer: Piramal Healthcare
 Branded Name: Clapton SR 120 mg

Dosage Type: Tablet Quantity; 10 Tablets Price (in Rs): 20.43

• Manufacturer: Torrent Pharmaceuticals Ltd.

Branded Name: Vasopten 120 mg

Quantity: 10 Tablets
Dosage Type: Tablet
Price (in Rs): 17.38

7. Drug Name

Verapamil 2.5 ml

Dosage type: Injection

Quantity: 2.5 ml Price (in Rs): 2.26

Branded Counterparts

• Manufacturer: Neon Laboratories Ltd.

Branded Name: Verobles 2.5 ml

Dosage Type: Injection
Price (in Rs): 8.23

8. Drug Name

Tolnaftate 10 mg
Dosage Type: Lotion
Quantity: 10 ml
Price (in Rs): 6.62

Branded Counterpart

Manufacturer: Fulford (India) Ltd.
 Branded Name: Tinaderm (skin) 10 gm

Quantity: 10 gm Price (in Rs): 11.42

• Manufacturer: Dabur India Ltd.

Branded Name: Tinavate (skin) 10 gm

Dosage type: Cream Quantity: 10 gm

Price (in Rs): 11.90

9. Drug Name

Betamethasone 0.5 mg Dosage Type: Drop Quantity: 15 ml

Price (in Rs): 9.32

Branded Counterparts

• Manufacturer: Glaxo Smith Kline Pharmaceutical Ltd.

Branded Name: Betnesol (E/E) 15 ml

Dosage type: Drop Quantity: 15 ml Price (in Rs): 11.00

• Manufacturer: Lark Laboratories Ltd.

Branded Name: Betalar Dosage Type: Drop Quantity: 15 ml Price (in Rs): 10.30

10. Drug Name

Theophylline 400 mg Dosage Type: Capsule Quantity: 10 capsules Price (in Rs): 9.62

Branded Name

• Manufacturer: Inventure (Intra Labs India Pvt. Ltd)

Branded Name: Theofil 400 mg

Dosage Type: Capsule Quantity: 10 capsule Price (in Rs): 49.90

• Manufacturer: Raptakos Porett & Co. Ltd.

Branded Name: Duralyn CR 400 mg

Dosage Type: Capsule Quantity: 10 Capsule Price (in Rs): 53.00

11. Drug Name

Tetracycline 250 mg Dosage Type: Capsule Quantity: 10 ca[psule Price (in Rs): 8.53 Branded Drugs

• Manufacturer: Acichem Laboratories

Branded Name: Tetracycline 250 mg

Dosage Type: Capsule Quantity: 10 capsule Price (in Rs): 6.00

Manufacturer: Cipla Limited
 Branded Name: Tetrabact 250 mg

Dosage Type: Capsule Quantity: 10 capsule Price (in Rs): 6.66

• Manufacturer: Neon Laboratories Ltd.

Branded Name: Neoline 250 mg

Dosage type: Capsule Quantity: 10 Capsule Price (in Rs): 8.00

• Manufacturer: Abott Healthcare Pvt. Ltd (APHL)

Branded Name: Resteclin 250 mg

Doasge Type: Capsule Quantity: 10 capsule Price (in Rs): 7.55

12. Drug Name

Carbamezepine 300 mg Dosage type: Tablet Quantity: 10 Tablet Price (in Rs): 6.68

Branded Counterparts

• Manufacturer: Sun Pharmaceuticals Industries Ltd.

Dosage Type: Tablet Branded Name: Zeptol Quantity: 10 Tablet Price (In Rs): 6.78

Manufacturer: Abott Healthcare Pvt.
 Branded Name: Mazetol Chew Tab 100 mg

Dosage Type: Tablet Quantity: 10 Tablet Price (in Rs): 9.64 • Manufacturer: Novartis Pharmaceuticals Ltd.

Branded Name: Tergrital 100 mg

Dosage Type: Tablet Quantity: 10 Tablets Price (in Rs): 10.48

13. Drug Name

Cefadroxil 1000 mg Dosage Type: Tablet Quantity: 10 Tablet Price (in Rs): 81.86

Branded Counterparts

• Manufacturer: Lupin Laboratories Ltd.

Dosage Type: Tablet

Branded Name: Odoxil OD 1000 mg

Price (in Rs): 134.84

14. Drug Name

Cefotaxime Sodium 500 mg

Dosage Type: Injection
Package Unit: 1 Vial
Price (in Rs): 14.36

Branded Counterparts

• Manufacturer: Abott Healthcare Pvt. Ltd.

Branded Name: Spinocef 500 mg

Dosage Type: Injection
Package unit: 1 vial
Price (in Rs): 42.94

• Manufacturer: Sanofi Aventis

Branded Name: Claforan 500 mg

Dosage Type: Injection
Package Unit: 1 Vial
Price (in Rs): 47.44

• Manufacturer: Alkem Laboratories Ltd.

Branded Name: Taxim 500 mg

Dosage Type: Injection
Package unit: 1 vial
Price (in Rs): 19.80

15. Drug Name

Ch;oroquine Phosphate
Dosage Type: Tablet

Quantity: 5 Tablet Price (in Rs): 6.42

Branded Counterparts

Manufacturer: Acron Pharmaceuticals

Branded Name: Malarbin 500 mg

Dosage Type: Tablet
Quantity: 5 Tablet
Price (in Rs): 5.00

• Manufacturer: Meditex Pharma Pvt. Ltd.

Branded Name: Chlorotek 500 mg

Dosage type: Tablet Price (in Rs): 11.32

• Manufacturer: Lark Laboratories (India) Ltd.

Branded Name: Larquin 500 mg

Dosage Type: Tablet Quantity: 10 Tablet Price (in Rs): 15.83

16. Drug Name

Cloxacillin 500 mg

Dosage Type: Capsule Quantity: 10 Capsule Price (in Rs): 19.86

Branded Counterparts

• Manufacturer: Lark Laboratories (India) Ltd.

Branded Name: Clopen 500 mg

Dosage Type: Capsule Price (in Rs): 25.00

• Manufacturer: Biochemistry Pharmaceutical Industries

Ltd.

Branded Name: Bioclox Caps 500 mg

Dosage Type: Capsule Quantity: 10 Capsule Price (in Rs): 21.61

• Manufacturer: Neon Laboratories Ltd.

Branded Name: Neoclox Caps 500 mg

Dosage Type: Capsule Quantity: 10 Capsule Price (in Rs): 26.41 17. Drug Name

Salbutamol 50 mcg

Dosage Type: Inhaler

Quantity: 1 Inhaler

Price (in Rs): 8.64

Branded Counterpart

• Manufacturer: Glaxo Smith Kline Pharmaceuticals Ltd.

Branded Name: Servent 50 mcg

Dosage Type: 1 Pack Price (in Rs): 440.00

18. Drug Name

Methyldopa 250 mg Dosage Type: Tablet

Quantity: 10 Tablet Price (in Rs): 11.72

Branded Counterpart

• Manufacturer: Sanofi Aventis

Dosage Type: Tablet

Branded Name: Sembrina 250 mg

Quantity: 10 Tablet Price (in Rs): 24.14

• Manufacturer: Mankind Pharmaceutical Pvt. Ltd.

Dosage Type: Tablet Quantity: 10 Tablet

Branded Name: Gynapres 250 mg

Price (in Rs): 26.60

19. Drug Name

Metronidazole 400 mg Dosage Type: Tablet Quantity: 10 Tablets

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Price (in Rs0): 7.35

Branded Counterpart

• Manufacturer: Abott Healthcare Pvt. Ltd.

Branded Name: Flagyl 400 mg

Dosage Type: Tablet Quantity: 15 Tablet Price (in Rs): 11.02

20. Drug Name

Insulin (Human) 40iu

Dosage Type: Injection

Quantity: 10 ml

Price (in Rs): 166.67

Branded Counterparts

Manufacturer: Abott India Ltd.
 Branded Name: Human Mustard 30

Dosage Type: Injection

Quantity: 10 ml Price (in Rs): 145.00

Manufacturer: Sanofi Aventis
 Branded Name: Insuman Rapid 40iu

Dosage Type: Injection

Quantity: 10 ml

Price (in Rs): 217.68 [19-21]

Conclusion

In the comparative analysis of generic drugs over the proprietary drugs, the analysis were made based on how they were developed. Proprietary drugs take lots of time to get approved as the new substance drug undergoes lots of testings (pre clinical as well as clinical testings). Also, the analysis was made based on the costs. Branded drugs are more expensive as seen in the cost estimate above. Generic drugs are cheaper option especially for long term treatments.

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