



“AN INVESTIGATION OF FACTORS INFLUENCING BRANDS PRESCRIPTION SUBSTITUTION IN PHARMACEUTICAL MARKET IN INDIA”

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ABSTRACT

Two drug products are deemed to be pharmaceutical equivalents if they have the same active ingredient, strength or concentration, dosage form, and route of administration. They may differ in shape, scoring design, release mechanisms, packaging, expiration time, and to some extent, labelling. Pharmaceutical alternatives are defined as drug products that have the same therapeutic moiety, but are different salts, esters, or complexes of that moiety, or are different dosage forms (eg. immediate release vs extended release) or strengths. Pharmacists often encounter questions from their patients concerning differences between branded and generic products. Furthermore, the availability of multiple generic products for a given branded medication may potentially lead to inappropriate generic substitution. For example, upon receipt of a prescription for Cardizem CD 240 mg, which does not indicate that the branded product must be dispensed, a pharmacist may face a dilemma as to which generic diltiazem products, if any, are suitable for substitution. In order to address these issues, a survey was conducted as to understand the current scenario for the demand of the Brand Prescription Substitution and a total overview was analysed on the basis of 205 respondents i.e. Pharmacy Stores. Researcher observed that change in brand prescription occur mainly because patient wants to buy generic drug and non-availability of brand strength or formulation of drug. Researcher also observed that change in brand prescription mainly given to respiratory drug and anti-histamine drug.

KEYWORDS: Brand Prescription, Brand Prescription Substitution, Generic drug, Generic substitution, Therapeutic substitution.

INTRODUCTION

Despite the efforts of governments, insurance companies and health care providers to enhance cost control, health expenditures in the developed world rise every year. The main reasons for this trend are the ageing of the population, growing expectations regarding health by the society as well as the continuous improvement in health technologies. Expenditures on pharmaceuticals are responsible for a major share in health expenditures and the percentage of pharmaceutical expenditures has been constantly rising for the last 30 years. India also faces the same trend of increasing health care and pharmaceutical costs. Pharmaceutical costs however, if expressed as a percentage of the total health expenditures are much lower in India, compared to other major European economies such as Germany, UK and France. Possibly, the relatively strict regulatory policy on the introduction and reimbursement of new drugs, the restrictive prescription policies (for example, regarding antibiotics) and the active stimulation of generic drug use might all be related to this phenomenon. In particular, a pharmacist may dispense the generic instead of the branded drug because the pharmacist gained more profit through discounts offered from manufacturers of generic rather than of branded drugs, there is no



available stock of the branded product at the pharmacy, and a branded prescription may not be (fully) reimbursed by the insurance company if the generic alternative is a lot cheaper, especially if there is a specific policy from the insurance company towards generics. Yet, despite the pressure of insurance companies on the broader use of generic drugs, the pharmaceutical expenditures in India are still increasing. One reason for this phenomenon is the relatively high level at which the producers still set the generic prices. Also, during the last years an increasing number of new branded drugs entered the pharmaceutical market, increasing the potentials for alternative means of treatment, branded prescribing and substitution between brands. According to Gumbs et al, the Dutch society could benefit with a health expenditure reduction of 71 million Euros if branded statin prescribing would be generically substituted in current users who are eligible for receiving generic treatment. Finally, in daily pharmacy practice, branded substitution is sometimes observed, where a generic prescription is being filled with the branded drug. Reasons for this include the level of severity of the disease, the personal preferences of the patient, the financial profit of the pharmacist as well as existing or perceived adverse effects related to generics in specific disease types. The aim of this study was to analyse the factors influencing the brand prescription substitution in India

BRAND SUBSTITUTION:

Substitution of a bioequivalent brand of the same or a different pharmaceutical item by the pharmacist without reference back to the prescriber where the patient agrees (when not disallowed by the prescriber). It is often termed as medication switches. Medication switches are most often thought of as changing a brand-name product to a generic drug. Switching also can mean the changing of one brand name product for another, or the switching of a generic medication to the same drug produced by another generic manufacturer. These can be initiated by your physician or pharmacy. One of the major directions of health policy is the attempt to contain expenditures on pharmaceuticals by encouraging substitution of generic for brand name drug products. Yet, a major marketing survey of prescribing and dispensing patterns in California in 1977 found relatively little drug substitution occurring, and in fact substitution of more expensive products occurred more frequently than did substitution of less expensive products. There are two types of substitution:

1. Generic substitution
2. Therapeutic substitution

1. Generic substitution

Generic substitution refers to the switching of a brand-name product to a generic product with the same active ingredients. The opportunity for cost savings emerges when expensive brand-name medications lose their patent protection and several generic medications are introduced on the market. The appearance of several manufacturers of the same generic leads a healthy price competition. Within months, the use of the expensive brand-name medication typically drops and the use of its generic counterparts increases markedly. The cost of 100 tablets of the brand-name cholesterol-lowering statin drug simvastatin (Zocor) in the 20-milligram strength is advertised as \$449.97 on the Web site of a large chain pharmacy. The same Web site lists the price of generic simvastatin in the same strength and amount for \$82.19, a difference of \$367.78. In the U.S., price reductions of 50 percent to 80 percent are common. Most states currently permit or require pharmacists to offer generic equivalents to consumers who present prescriptions for brand-name drugs and require consumers to give consent or be informed of generic substitutions.

2. Therapeutic Substitution

With therapeutic substitution, a medication previously determined to be therapeutically equivalent to a second drug, even though it is not chemically identical to the prescribed drug, is automatically dispensed by the pharmacist without contacting the prescriber for authorization. This is an accepted practice in hospitals, and most, if not all, hospitalized patients have experienced therapeutic substitution. A committee of physicians and pharmacists, usually called the Pharmacy and Therapeutics Committee,

determines therapeutic equivalence and what medications can be substituted. Therapeutic substitution is not a state- or federally regulated activity. Government health plans may require therapeutic substitution, and private sector health plans offer economic inducements for what amounts to therapeutic substitution. In private sector plans, the preferred drug in a family of drugs may be based only on the lowest-contracted price, rather than an evaluation of comparative safety and effectiveness by physicians and pharmacists. This is accomplished by offering consumers lower co-payments for preferred drugs.

RESEARCH METHODOLOGY:

Deciding the sample size and sampling technique is an important part for any research. There are various methods for deciding the sample size. For this study, the data collection was done by Convenience Sampling. Researcher used Structured Questionnaire for collecting primary data. The questions were framed keeping in mind the objectives of research. The questionnaire was filling by pharmacist who have medical store and the data was collected by personal interview in the form of written responses of the questionnaire. Total sample size was 206 pharmacists who have medical store. For the analysis of the data, researchers used basic techniques of Statistics such as mean, standard deviation, variance; for hypothesis testing researcher used SPSS software and used Chi-square test and regression analysis.

RESEARCH HYPOTHESIS:

1. Change in brand prescription occur mainly because of patient ask for generic drug followed by unavailability of brand strength or formulation of drug.
2. There is significant association between source used for drug substitution and people requesting for change in brand prescription.
3. Change of brand prescription is mainly given to Respiratory drug followed by Histamine drug.

DATA ANALYSIS & HYPOTHESIS TESTING:

Testing of Hypothesis 1: Change in brand prescription mainly because of patient want to buy generic drug followed by unavailability of brand strength or formulation of drug.

Researcher uses multiple regression analysis to test this hypothesis at 95% level of confidence and 5% level of significance. Multiple Regression equation is as follow,

$$Y=a+b_1X_1+b_2X_2+b_3X_3+b_4X_4+b_5X_5+b_6X_6$$

Where,

X₁=price of prescribed drug is high

X₂=non-availability of brand

X₃= non-availability of brand strength or formulation

x₄= promotion

x₅= want to buy generic drugs

x₆= want to buy branded generics

Table No. 1: Coefficients

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
1 (Constant)	1.230	.322		3.819	.000
Price of the prescribed drug is high (X1)	.102	.079	.099	1.296	.196
Unavailability of the prescribed drug (X2)	.173	.070	.183	2.466	.015

Unavailability of the formulation or brand strength (X3)	.190	.069	.204	2.762	.006
Promotions (X4)	-.042	.062	-.047	-.667	.506
Want to buy generic (X5)	.191	.071	.197	2.687	.008
Want to buy branded (X6)	-.024	.054	-.028	-.441	.660

a. Dependent Variable: Patient's request for changing their prescription

From the above Table No. 1 of Coefficient, multiple regression equation is as follow,

$$Y = 1.23 + 0.102x_1 + 0.173x_2 + 0.190x_3 + (-0.042x_4) + 0.192x_5 + (-0.024x_6)$$

As the significance value of X6, X4 and X1 is more than 0.05, hence we reject those parameters. Hence new regression equation is as follow,

$$Y = 1.23 + 0.173x_2 + 0.190x_3 + 0.191x_5$$

Hence from the above equation researcher can infer that switching to Generic medicines is main reason for the substitution in prescription of medicines followed by unavailability of brand strength or formulation and finally unavailability of branded medicines.

Testing of Hypothesis 2

There is significant association between source used for drug substitution and demand for brand substitution.

Table No. 2 Chi-Square Tests

	Value	Df	Asymp. Sig. (2-sided)
Pearson Chi-Square	28.090 ^a	20	.107
Likelihood Ratio	31.062	20	.054
Linear-by-Linear Association	4.737	1	.030
N of Valid Cases	206		

a. 19 cells (63.3%) have expected count less than 5. The minimum expected count is .36.

Researcher uses chi square test to test this hypothesis at 85% level of confidence and 15% level of significance.

From Table No. 2, researcher found that the Pearson chi square's P-value is 0.107 which is less than 0.15 ie level of significance; hence researcher conclude that sources used for drug substitution by chemist and patients requesting for change in prescription are closely associated.

Table No. 3: Patients request for change in prescription * Rely on for substitution by chemist Crosstabulation

		Chemist rely on for brand substitution						Total
		1mg	Netmed	Medplus	Ask apollo	Medstore	Self knowledge	
Patients request for change in brand prescription	Never	5	0	1	1	3	5	15
	Rarely	15	4	6	0	8	39	72
	Sometimes	22	2	9	2	1	28	64
	Very often	13	1	7	2	2	13	38
	Always	9	0	1	0	0	7	17
Total		64	7	24	5	14	92	206

Out of the total 206 respondents, 72/206 customer request for change in prescription, hence chemist offered brand substitution; out of which 39/72 chemist rely on self-knowledge for brand substitution. 64/206 customer request for change in prescription, hence chemist offered brand substitution; out of which 28/64 chemist rely on self knowledge for brand substitution and 22/64 chemist rely on 1 mg app for brand substitution. It is also observed that 92/206 chemist rely on self knowledge for brand substitution and 64/206 chemist rely on 1mg app for brand substitution.

Testing of Hypothesis 3: Change of brand prescription is mainly given to Respiratory followed by Histamine and Antacidtherapy areas.

Researcher uses multiple regression analysis to test this hypothesis at 90% level of confidence and 10% level of significance. Multiple Regression equation is as follow,

$$Y=a+b_1X_1+b_2X_2 + b_3X_3+ b_4X_4 +b_5X_5 +b_6X_6$$

Where,

- x₁ = Substitution in Anti pyretic anti inflammatory
- x₂= Substitution in Antacid,drug for hyperacidity
- x₃=Substitution in Anti–diabetic
- x₄= Substitution in respiratory
- x₅=Substitution Anti-histamine
- x₆= Substitution in Hypertension
- x₇ = substitution in anti inectives

Table No. 4: Coefficients

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	2.031	.283		7.180	.000
Substitution in anti pyretic category (X1)	.029	.064	.035	.460	.646
substitution antacid category (X2)	.124	.065	.145	1.891	.060
substitution antidiabetic category (X3)	-.125	.105	-.131	-1.190	.236

substitution respiratory category (X4)	.185	.109	.184	1.700	.091
substitution antihistamine category (X5)	.181	.097	.173	1.868	.063
substitution hypertension category (X6)	-.088	.100	-.088	-.883	.378
Substitution antiinfective category (X7)	-.026	.083	-.026	-.314	.754

a. Dependent Variable: Patients request for brand substitution

$$Y = 2.031 + 0.029 x_1 + 0.124x_2 + (-0.125x_3) + 0.185x_4 + 0.181x_5 + (-0.088x_6) + (-0.026x_7)$$

Since the value of x_1, x_3, x_6 and x_7 is greater than 0.1 we have excluded those values. Hence new regression equation is as follow,

$$Y = 2.031 + 0.124x_2 + 0.185x_4 + 0.181x_5$$

Thus, change in brand prescription is mainly given for respiratory drug followed by anti – histamine drug and antacid therapy drug.

CONCLUSION:

Researcher limited the analysis of this study to retail/ chemist claims only. Overall finding of research suggests that switching to generic medicines is main reason for the substitution in prescription of medicines followed by unavailability of brand strength or formulation and finally unavailability of branded medicines. It was also observed that that sources used for drug substitution by chemist and patients requesting for change in prescription are closely associated, it means that whenever patient request for brand prescription, the chemist recommend substitution based on his/her own self knowledge. Finally researcher observed that change in brand prescription is mainly given to respiratory drug and anti-histamine drug. Researcher suggests that company should develop marketing strategy to chemist so that they should push the drug as generic drug in the market, as self-knowledge is preferred by chemist to recommend generic drug to the patient.

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