

**OVERVIEW ON OVER-THE-COUNTER DRUGS: COMPARISON BETWEEN
GENERIC AND BRANDED DRUGS IN INDIA**Priyanka Narendra Warambhe^{1*}, Dr. Suhas Padmane² and Dr. Sheelpriya Walde²^{1,2}Gurunanak College of Pharmacy, Nagpur.***Corresponding Author: Priyanka Narendra Warambhe**
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ABSTRACT

In recent years there has been an increasing trend in self-medication with non-prescription drugs, sometimes referred to as over-the-counter (OTC) medicines available in pharmacies and retail outlets. Self medication also has advantages for healthcare systems as it facilitates better use of clinical skills of pharmacists, increases access to medication and may contribute to reducing prescribed drug costs associated with publicly funded health programmes. The present study was conducted to compare the quality and price of generic drug product to their expansive popular brands (branded) product manufactured by the same pharmaceutical company in India.

KEYWORDS: Over the counter medicines, generics, brands, prescription.**1. INTRODUCTION**

Medicines are the vital components of therapeutics which are manufactured, distributed and sold to the patients under various regulations like Drugs and Cosmetics Act and Drug Price Control, 1945 and the market in India in on the rise.^[1] Over the counter drug are the drugs that are purchased without prescription. There are currently more than 300000 different OTC drugs available. The Indian OTC market ranks 11 th in terms of market size globally. The Indian OTC market is extremely competitive at present.^[2] In India, though the phrase has no legal recognition; all the drugs that are not included in the list of 'Prescription Drug' are considered as non-prescription (OTC) drug. In India, the import, manufacture, distribution and sale of drugs and cosmetics are regulated the Drugs and Cosmetics Act. Pharmacist and pharmacist attendants play an important role in fostering self-medication among the people.

In India, it is possible to buy prescribed and non-prescribed drugs with or without prescription from a wide variety of sources. OTC medicine provide consumers safe and effective treatment for commonly occurring conditions saving them time and money that might otherwise be invested in other, more expansive health service. Generic drug provide the opportunity for major saving in healthcare expenditure since they are lowering in cost than branded. The present study was conducted to compare the quality and price of generic drug product to their expansive popular brands (branded) product manufactured by the same pharmaceutical company in India. Almost all medicine in India, are sold under a brand (trade) name and medicine are called as branded medicine or branded-generic. The study was

undertaken to evaluate the dispensing pattern of OTC drugs in retail pharmacies in, Nagpur. Pharmacists have to be trained and educated regarding rationale dispensing of drugs.^[3]

As the general rule OTC drugs have to be primarily used to treat a condition that does not require the direct supervision of a doctor and must be proven to be reasonably safe and well tolerated. OTC medicine can help you feel better by helping to treat or prevent health problem, such as allergies, constipation, cold, flu and nausea. However sometimes OTC medicine can cause unpleasant effect. These adverse effect include side effects, drug-drug interaction, food-drug interaction, and allergic reactions. This trends is increasing and is expected to reach 9th position within next 5 years.^[4] Since Indian patients have huge tendency of self treatment. The Indian market is characterized by a huge demand for OTC drugs. In India, through the OTC phrase has no legal recognition, all the drugs that are not included in the list of prescription are considered as non-prescription drugs.^[5] Prescription drugs are those that fall under two schedule of the drug and cosmetics rules 1945: schedule H and schedule X. Schedule H and X are drugs which can be sold only on the prescription of a registered medical practitioner.^[6] This legal requirement is made to prevent self medication of medication with OTC analgesics such as paracetamol among children and adolescents is increasing. OTC medication offers advantages like easy access to medicines, self management of minor ailments with the involvement of pharmacists, and utilization of available resources. In India, OTC related adverse effects, abuse, and hospitalizations are on the rise. Hence, this study was

undertaken to evaluate the dispensing pattern of over the counter drugs in retail pharmacies. OTC medicines have played a significant role in expanded access to safe and effective treatments in developing regions of the world. Many people in these regions do not have access to health services and rely heavily on self-care and self-medication, and OTC medications provide valuable resources to address health conditions.^[7]

1. 1 Pharmacist Role in Over-the-counter Drug Use

Pharmacists are one of the most accessible health care professionals that can help consumers make the most educated choices about the use of OTC drugs. Since pharmacists are available at the point of purchase, they can assist the patients in the In today’s OTC drug market, there is a wide variety of products with multiple active ingredients, a vast array of brands and their line extensions. Advertising is one of the marketing strategies used by the pharmaceutical companies to introduce these products to the consumers. Selection of appropriate OTC products, help them understand detailed health information and refer the patient to a physician, if necessary.^[12]

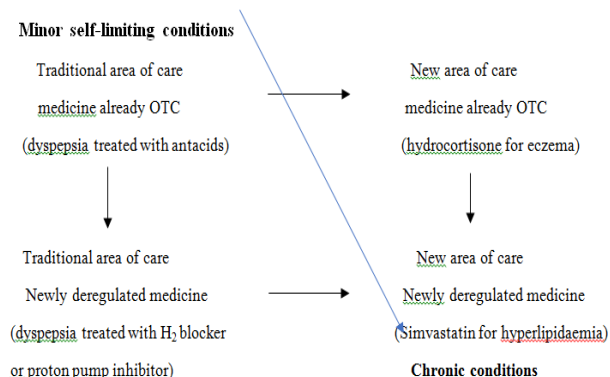


Figure 1: Progress from Prescription only medicine to pharmacist and overall cultural change.

1. 2 Trends in Over-the-counter Drug Advertising

Pharmaceutical manufacturers spend a substantial amount of time and money toward the development of efficient advertising strategy. According to the literature, close to \$3 billion was spent to advertise OTC drug brands. The spending on different media was as follows: Network television(\$834.5 million), national magazines (\$684.7 million), and cable television (\$668.2 million). There are certain advantages associated with the advertising of pharmaceutical products. It allows the consumers to gain knowledge about the drugs and thereby makes them capable of taking control of their health Advertising contributes to the healthcare field by providing people with a variety of choices. It helps them recognize between the different options available to them, raises awareness of conditions and potential treatment options among the patients. It is also considered to provide a guarantee of quality, reliability, consistency and facilitating product search and informed selections by the consumer.^[19]

1. 3 Literature Review

Over the counter (OTC) drugs are medicines that are available for sale directly to a consumer. According to the U.S. Food and Drug Administration (FDA), OTC drugs are defined as the medications that can be used safely and effectively by the general public even without a prescription. Comparison prices of brand and generic medicine manufacturing same company having same category of drugs are mentioned in below following table.

Table 1: Comparison prices of brand and generic medicine.

Sr. no	Name of medicine	category	Unit	Generic name	Brand	Brand price	Difference in price
1	Aceclofenac + Paracetamol (100 mg + 500 mg) tablet	Analgesic	10's	14.49	Zerodol-p (Ipca)	38.5	28.1
2	Acetaminophen+ Tramadol hydrochloride (325mg+375mg) Film coated tablet	Analgesic	10's	8.16	Ultacet (Johnson & Johnson)	142	133.8
3	Amikacin 100 mg inj	Antibacterial (Antibiotic)	10's	15.4	Amiject (Alkem)	27	11.96
4	Cefixime (50mg/5ml) dry syrup	Antibacterial (Antibiotic)		25.6	Taxim-O (Alkem)	42.21	16.28
5	Glimepiride 1 mg tab	Anti-Diabetic	10's	3.48	Glimestar-1 (mankind)	22	18.52

6	Insulin Injection IP 40 IU/ml (Insulin Human Recombinant)	Anti-Diabetic	10's	118.93	Heminsulin (Eli Lilly & company)	141.24	22.33
7	Albendazole (200mg/5ml) syrup	Anthelminitic	10's	14.3	Band Mankind	17.1	2.8
8	Omeprazole 20 mg Film coated Tablets	GERD	10's	10.3	Omez (Dr. Reddys)	36.36	26.33
9	Pentaprazole 40mg film coated Tablets	GERD	10's	9.97	Pan-40 (Alkem)	120	110
10	Atenelol 50mg Tablets	Anti Hypertensive	10's	55.57	Aten 50 (Zydus Cdila)	24.4	31.17
11	Alprazolam 0.5mg Film Coated Tablet	Anti-anxiety	10's	3.97	Anxit (Micro Labs) 1x 15	34.96	30.99
12	Dexamethasone tablet I.P. Strenght 0.5 mg	Anti Inflammatory/ Anti- allergic	10's	3.69	Dexona (Zydus Alidac) 1 x 20	3.78	0.09
13	Betamethasone Tablet IP 0.5 mg	Anti-fungal		6.74	Betnesol (gsk)	8.1	1.36

Objective and procedure of the study included commonly used medicine category: analgesic antipyretic, cough, cold, allergic drug, antibiotics, ophthalmic products, vitamins, herbal formulations, dermatologically products etc. manufactured in branded and branded-generic versions by the same company were selected. Price to patient and price to retailers were found for pair of medicine. Both quantitative and qualitative analysis were performed method prescribed in IP.

Retailer margin for branded medicine were in the range of 25-30% but for their branded- generic versions manufactured by the same company it was in the range of more or double than its original price i.e no fixed margin. Price to patient for the branded version of this category of drugs was higher by 41%, 33% 30% 14% and 10% than branded-generic. Average price of drugs are given in following chart-1

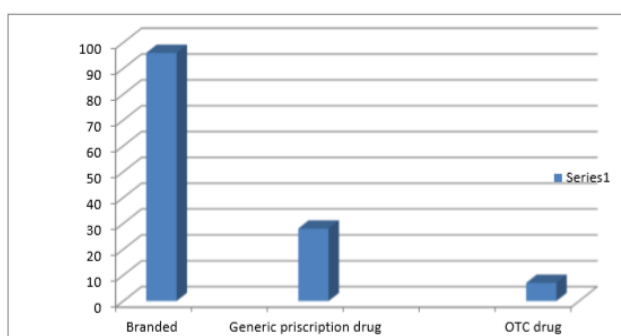


Chart 1. Average Price of Drugs.

2. AIM AND OBJECTIVE

Over the counter drugs (OTC) are sold without the prescription of a registered medical practitioner. The use of over the counter drugs is growing rapidly in India. The purpose of this study was to determine price variation between different brands by manufacturing same category of drugs or products. To compare and evaluate the price and quality of Branded and Branded-Generic equivalent of some commonly used medicine manufactured by the same pharmaceutical company in India. Although brand medicines in India appear cheap when compared with international prices, however the brand medicines in India are expensive in comparison with generic medicines.

The brand medicines despite being expensive are preferred over generic medicines by the prescribers due to exhaustive marketing practices by the manufacturers. Although generic medicines are available at affordable prices they are not preferred over brand medicines. The price sensitivity for medicine appears to be very low. Generic medicines are less popular for various reasons, primarily due to marketing techniques of during the prescribers brand medicine.⁴

3. METHODS AND MATERIALS

The study was conducted in retail pharmacies in Nagpur region. The duration of the study was for a period of three months. The common complaints for which the patients frequented ask to the pharmacist were observed and recorded. The investigator personally interviewed the patients between 6pm to 9pm, near the respective pharmacies. During this study period around numbers of patients visited pharmacies without prescription. The drugs supplied to patients by private pharmacies without

prescription was recorded. Data was analysed by descriptive statistics using Microsoft Excel. Over-the-counter (OTC) medications drugs available to consumers without a prescription play an increasingly vital role in our healthcare system and are the most prevalent means of treating the majority of common health problems in the United States. There are over 80 therapeutic categories of OTC drugs. The survey study was conducted with an aim to compare and evaluate the price and quality of Branded and Branded-Generic equivalent of some commonly used medicine manufactured by the same pharmaceutical company in India. Broad therapeutic classes of OTC medicine are as follows in figure 1.^[9]



Fig. 1. Broad therapeutic classes of OTC Drugs.

Top companies who sales OTC products are listed as below in following table 2:

Table 2- Top 10 companies sales OTC products.

Ranking	Company	Total sales \$
1	Novartis	57996
2	Pfizer	49605
3	Sanofi	41114
4	Roche	48039
5	Merk	42237
6	Johnson and Johnsons	74331
7	Asterazeneca	26095
8	Galaxosmithkline	35825
9	Teva	20272
10	Gilead	24474

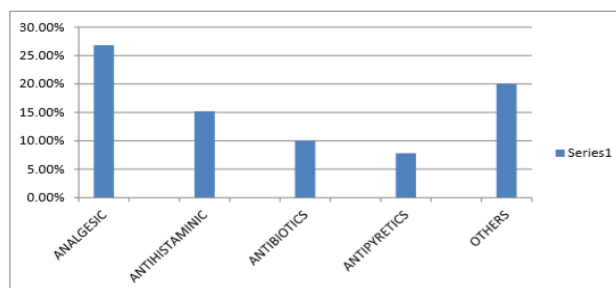
3.1. Benefits and challenges of wider availability of otc medicines.

As noted earlier the rotational for deregulation of medicine is said to have been driven by government, the profession and the industry. From the governments perspective deregulation is part of a philosophy to increase safe and convenient access to medicines, empower the public and encourage them to take greater responsibility for their own health. The challenge therefore is to empower pharmacists and their staff to provide more directive advice to people buying medicines, without compromising the principles of increased public access to medicines and public empowerment. Indeed, there is little evidence at all for many of the much hyped and advertised cough and cold remedies traditionally sold.^[18]

3.2. DATA ANALYSIS

Because of increasing trends of using OTC drugs people asks for the various medication. During the data analysis the average price of drugs are mentioned in above chart-1 and majority of drugs that comes under antipyretic, analgesic, anti-inflammatory, anti-allergic category are asked by patient and such type of drugs are dispensed by pharmacist without proper prescription. Most commonly dispensed OTC drugs were analgesics (26.8%). The other categories of medications dispensed were antihistamines (15.2%), antacids (14.8%), antibiotics (10%), antipyretics (7.8%), Oral contraceptive (OC pills) (5.09%) and others (20%). The commonly dispensed antibiotics were Cefadroxil (250mg) for dental infection and Levofloxacin (500mg) for upper respiratory tract infection. The most common complaint for the use of OTC drugs was pain (25%). It was noted that 55.09% of the dispensed drugs belonged to schedule H. However, 13% patients were aware regarding the harmful effects of drugs. Different categories of medication dispensed in % given in following chart -2

Chart 2 - CATEGORIES OF MEDICATION DISPENCED



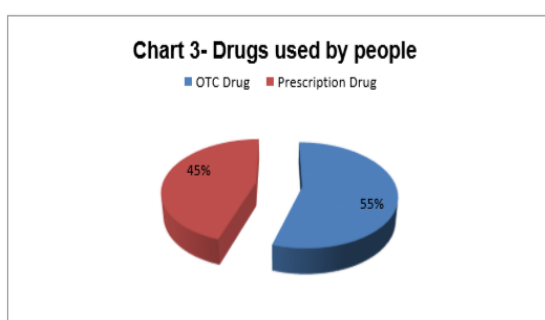
Above drugs can be used for commonly ailment like headache, fever, constipation, diarrhoea, acidity, skin problem, muscle/joint pain, cold/cough etc.^[10]

4. RESULT AND DISCUSSION

Generic drugs are copies of brand name of drugs. They are just safe, are equal in quality, and much lower in cost than brand name drug. Generic drug manufacturers do not need to invest as much money on research, development, testing, and approval processes as brand name drug manufactures. Also, they do not spent millions of dollars on promotion and advertising. Over 60% of prescription filled were generic drugs, but they only accounted for 24.5% of the \$22.1billion that candidates spent on prescription drugs. By buying generic drugs, you can save your own hard earned dollar's and help reduce costs to your health care plan. for ex-

Brand name (Crestor)	Generic name (Rosuvastatin calcium)
Drug cost \$ 173	Drug cost \$ 45.90
Plan pays \$ 138.40(80%)	Plan pays \$ 36.72 (80%)
Member pays \$ 34.60 (20%)	Member pays \$ 9.18 (20%)

Generic drugs over brand-name drugs has been widely discussed in literature, their market pricing and subsequent use. Analysis of literature shows that drug development and testing costs, degree of health care privatization. This literature review focuses on a) analyzing the policies and expenses associated with gaining approval for brand-name and generic drugs, and their subsequent influence on drug pricing; and b) comparing and contrasting government controls and policies. Generic drugs contain the same active ingredients present in brand-name drugs, but often differ in peripheral features that do not impact their bioavailability. Market prices of generic and brand-name drugs very noticeable difference in prices between brand-name and generic drugs exists in several countries around the world. Brand-name drugs have been shown to be priced 20 % higher than generic.^[11]



In this study also, the most commonly dispensed OTC drugs were analgesics of which NSAIDS were the commonest. The other categories of drugs dispensed were antihistamines, antacids, antibiotics, antipyretics and miscellaneous. The most common illness for the purchase of OTC drugs was pain which included dental pain, myalgia and body pains. OC pills were also dispensed for the postponement of menstrual cycles. Other illness were headache, gastro intestinal problems like diarrhoea, constipation, respiratory illness like cough, fever. In this study, antibiotics were mainly dispensed for fever, cough and dental infection. Ceftriaxone, Amoxicillin antibiotics and prescription was given for 3-7 days and Coamoxiclav were most commonly dispensed duration. In this study levofloxacin was most commonly dispensed antibiotic and the duration of prescription was only for 1-2 days. A study showed that OTC drugs were commonly purchased by females of mean age, 37 years. In this study, there was male preponderance (70.83%) and mean age was 42 years. This difference may be due to the fact that the study was conducted in a small area. There might be a male preponderance in that area. The distinct feature of this study was that 55.09% of the drugs belonged to Schedule H category which was not supposed to be dispensed over the counter. Thirty-four percent of the drugs were dispensed in fixed dose combinations (FDC) and the most common FDC were diclofenac and paracetamol. The other findings from this study were that drugs were dispensed appropriate to the disease condition. The alarming observation was that the

pharmacists did not ask about drug allergy and the existing co-morbid conditions while dispensing the OTC drugs. Appropriate instructions were not given to all patients and adverse effects of the drugs were not explained. Drugs were not dispensed according to the appropriate dosage regimen. Most commonly dispensed OTC drugs were analgesics (26.8%). The other categories of medications dispensed were antihistamines (15.2%), antacids (14.8%), antibiotics (10%), antipyretics (7.8%), Oral contraceptive (OC pills) (5.09%) and others (20%). The commonly dispensed antibiotics were Cefadroxil (250mg) for dental infection and Levofloxacin (500mg) for upper respiratory tract infection. The most common complaint for the use of OTC drugs was pain (25%). It was noted that 55.09% of the dispensed drugs belonged to schedule H. However, 13% patients were aware regarding the harmful effects of drugs. Drugs used by people in % is mentioned in above chart - 3.

5. LIMITATION

The limitations of this study are its short duration and that socio economic and educational status of participants were not taken into consideration.

6. CONCLUSION

The most commonly dispensed OTC drugs were analgesics. Most of the patients were not aware of the contraindications or undesirable effects of the dispensed drugs. It was noted that majority of the dispensed drugs belonged to schedule H. It can thus be concluded from the study that more awareness of patients and pharmacists about OTC drugs are required to prevent the harmful effects of the same. This could be attained through the effective use of mass media and regular training of pharmacists. Also, drug regulatory authorities should strictly enforce laws pertaining to drug dispensing. The use of OTC drugs is alarmingly high in Nagpur. Pharmacists have to be trained and educated regarding rationale dispensing of drugs. The need for promoting the appropriate use of drugs in the Indian health care system is important. This can be achieved through educational, regulatory and managerial strategies. Commonly used OTC drugs in percentage is mentioned in following table -3.

Drugs	%
Analgesic and antipyretic	65.00 %
Cough suppressant	35.62 %
Antibiotics	75.82 %
Antacids	72.30 %
Dermatological products	40.10 %

7. FUTURE SCOPE

There, are nearly thousand number of pharma industry, involved in manufacture and sales of brand medicines. Quality control and Quality assurance of the products available in the market cannot be effectively done as it requires huge infrastructure and drug analysis. Hence Quality assurance and Quality control are the in house

responsibility of the industrialist. However they are also cross checked by the Drug control department in between Hence the qualities of medicines are certified by the analyst appointed by the company.

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