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CHAPTER - II

REVIEW OF LITERATURE

2.1 INTRODUCTION

Science of marketing programme in order to be successful must address important aspects of marketing mix, which could have right market, quality product, distribution network strong dose of promotion, at right price. There are basic categories of pharmaceutical companies. Research based companies, Generic Drug manufacture and OTC (over - the – counter) category, Companies are active in more than one categories mentioned above, companies like. Ranbaxy and GSK are involved in more than one category o business. The unique feature of pharmacy industry is that, it is the most fragmented market in the country. The place of retail chemist is the real criteria of the market response, as the retailer deals with ethical drugs; he deals with OTC products also (over the counter products). Hence the retailer is expected to choose their own promises in close vicinity of hospital. In this chapter a critical review of literature concerning this research, published & unpublished is presented. Since academicians, researchers & professionals have contributed, which come in the from of articles and books. Since this study was focused on the marketing strategies the literature reviewed was narrowed down to marketing strategies for OTC pharmaceuticals products. There is evidence that more and more people are taking greater responsibility for their health care system. Self diagnosis & self treatment are making a comeback OTC medicines are the easiest & most common alternate for self treatment as everyone having some experience in using & purchasing OTC medicines. Hence the research on the topic OTC marketing strategies.

This chapter contains the reviews of empirical studies on OTC drugs marketing in research area. In addition to this various aspects of conceptual framework of OTC drugs and self-medications are studied such as self medication in chronic and acute ailments. Role played by chemists, doctors and marketing personnel of the sample companies in making the OTC products available, affordable, accessible without the supervision of doctors and creating awareness through advertisements .classification of OTC categories and problems of chemists and doctors in ensuing risk free self medication in India.

2.2 REVIEW OF BOOKS

Subbarao Chagmati (2007)\textsuperscript{1} in his book on “Pharmaceutical Marketing in India” concept strategy cases has critically examined the Pharmaceutical marketing in Indian context. He had described the overviews of the Indian. Pharmaceutical market with nine ‘P’ goes beyond mega marketing and maxi marketing understanding nine P’s - product , Price, Place, Promotion, Personal selling prescription, policy, power and public relation is indeed critical for creating and extending successful strategies in Pharmaceutical marketing. He comments on his Pharmaceutical promotion will be more challenging than now, only innovative marketers with differentiation. Strategies are likely to be successor.

The pharmacy industry will continue with more mergers & acquisition of brands as well as companies to achieve synergies pharmacy. He has beautiful “Ten” major principles in achieving marketing excellence like customer orientation, quality innovation, differentiation competence segmentation strategy, competition an analysis new product development. Building a winning team & the book talk about the successful
Marketing strategies used by organization in OTC marketing. The author also suggests that marketing which is changing with rocket speed need more attention in pharmaceutical products. Direct-to-consumer advertisements can be a new tool in promoting prescription drugs to consumers directly to tap market, as the health care market has huge opportunity for Indian pharmacy companies. The author also suggested that sales force in pharmaceutical industry should be trained efficiently not only on product knowledge but also on competitive advantage and price-related area, which will help companies market the products at a larger scale.

**Mickey Smith (2001)** in his book “Pharmaceutical Marketing in 21st Century” has narrated the change taking place in pharmaceutical industry today within the world of Pharmaceuticals marketing in serious transition the book goes beyond 4 Ps of marketing. The book provides lucid but brief review of excellence in Pharmaceutical industry. The author also points out on marketing medicines for self medications gives new area of the study. More and more pharmaceutical companies implementing the switch strategy of prescribed to OTC, one because there is world wide trend person to take charge of their own health secondly the companies understand that after patient expiry of a drug, the drug can be switched to OTC. The demand for a branded and well-known drug is very high and this can be capitalized more when the switch is successful, sales of such drugs had increased tremendously. The author also narrates the issue of trade names distribution and advertising OTC drugs. One important comment came out of the book was consumer and other organizations have the role of criticizing and complaining about promotion of prescription and non-prescription drugs. Direct to consumer advertisement are playing an important role in educating consumers on their health, secondly improving relationship with doctors and above all in minor ailments it will induce safe self medication using OTC products. He also states that Pharmacists should welcome the number of medicines available for self medication and direct to consumer Advertisements will brings people into pharmacy. In study further reveals that it is desirable to encourage self medication and every attempt should be made to ensure its appropriate use to guard against any unacceptable risks it may entail. Consumers generally do use non-prescription medicines (OTC) with responsibility & safety. The author also suggests pharmaceutical companies create awareness through advertisements and to bring more, affordable, accessible, and quality products in treating minor ailments and lower down the cost of medicines and hospitals.

**Anshal Kausherh (2006)** in his book on “Pharmaceutical Marketing, Emerging Trends” Pharmaceutical marketing explains on the changing global economy and specifically with more concern over healthcare. The Pharmaceutical industry is besieged with number of issues – competition from generic drugs, shrinking patent protected life, change healthcare policies of Government and Global competition. Branding strategies of OTC drugs would differ from branding strategies for prescription drugs. Building a brand for a prescription drug is a relatively difficult task because a typical presentation has a few years left before its patents expires then the alternative with companies is to invest in building brands in OTC drugs which can be made available over the counters. The author also emphasis on the new strategy of reaching out the consumers. DTCA - Direct to consumer advertising. DTCA can provide a competitive advantage particularly is market with OTC alternatives are available also the pace of Rx to OTC switches one bound to accelerate as more blockbuster patient expires making a brand differentiation ever more crucial. Pharmaceutical companies and their agencies will respond with new creative solutions, in near future and more of innovative advertising & media campaign will be
seen. The author emphasizes on a rational approach of marketing OTC drugs as FMCG Products using all those tools which are generally used in marketing a FMCG products and creating brands. The author also warns the Pharmaceutical companies about the competition across boundaries and suggests crafting a competitive strategy which is consumer centric and country specific.

**Dr. Atmaram Pawar (2007)** in his book titled “A handbook on community Pharmacists” (Exclusively for Chemists & Druggists) is basically a training book for chemists and druggist in Maharashtra. The author had researched the working pattern of chemists and problems faced by chemists in convincing and counseling the customers. The author reveals the existence of pharmacists and their different roles which are not played by the pharmacists and chemists. He points that Pharmacists are underutilized in India as they are only involved in pharmaceutical trading and not in pharmacy care through patients counseling. Hence continuous training of pharmacist is the only option for updating the knowledge of pharmacist. The author hints on the concepts of community pharmacist, role of pharmacist in global market place where retail pharmacy formats like chain of pharmacists are seen growing. This book hints on the practice of self-medication by rich and poor, educated and uneducated, rural and urban masses is paramount, which may results in sever health complications if OTC Drugs are not undertaken supervision, so the pharmacists role as a counselor becomes important in educating the patients who ask for OTC Drugs on their half knowledge. Except few drugs under schedule K, all the legal rights for dispensing of medication preside with pharmacist. The author suggests a model of community pharmacists model for country like Indian with varied lifestyles. The model emphasis on effective use of Patient information leaflet(PIL) and Pictograms, medication card and patient medication record(PMR) for effective functioning of the model.

**Umesh Vyas (1994)** in his project titled “A project on innovative marketing policy “had narrated the changing pharmaceutical marketing process. Though Parma marketing has occupied a large momentum in a decade long time, leading to brand promotion through personalized communication pharmaceutical selling is a typical example of marketing communication to a distinguished segment of the society i.e. Doctors through personalized communication where brands are promoted through audio-visual, impact of displaying printed material and detailing. The research also reveals the importance of drugs being switched from prescription (Rx) to over the counter (OTC) status has given a new perspective of consumer behavior issues. The researcher also suggests that the pharmaceutical companies are also becoming vibrant and changing as per the changing environment. The researcher also suggests innovative marketing strategies play a vital role in making a drug successful and for this only traditional marketing tool will not help. Marketing of pharmaceutical products go beyond on detailing doctors and visiting chemists for orders and schemes. Doctors, chemists and Pharmaceuticals companies need to work together in bringing effective products so that marketing policies using the 4p of marketing management are planed and implemented successfully in any market. The researcher also reveals that the large organizations will be comfortable in doing this kind of exercise as they can invest in marketing activities and changing the rules and policies, either it is making more OTC brands available or marketing Prescription drugs through Medical Representatives. The study also throws light on the attitude of marketing managers towards various changes in marketing of products.
2.3 REVIEW OF PHD THESIS

MeeraVijay (2006)\(^6\) in her thesis on “A study on impact of direct to consumers pharmaceutical marketing under Indian conditions,” this study was conducted in Mumbai with the objective to have all India representation on Direct to consumer pharmaceutical advertising in chronic and major ailments. This study was mainly focused on the advertisements in Indian pharmaceutical conditions. The researcher had studied the impact of Advertisements on Consumers especially positive impact. The researcher also studied the Consumers perception on minor ailments that could be self medicated without a doctor consultation and other major ailments where doctor’s consultation is important. But at the same time Advertisements in major ailments like Asthma, Blood Pressure, Cardiac Unrest etc can be viewed positively by consumers Under Indian conditions. Direct to consumer pharmaceutical help seeking advertisements will result in a win-win situation for all the participants in health care system. She also warns on permitting Direct to consumer pharmaceutical reminder advertisements may not be safe in country like Indian where literacy levels and varied income groups is of big concern hence study on OTC Products which aims to induce a self medication with safety, affordability and availability of drugs in reach on the poor.

The study also revealed that under Indian conditions, Direct to consumer pharmaceutical help-seeking advertisements may be simple, attractive and may motivate consumers to seek doctor opinion rather than self medicate. Secondly it the researcher also suggests the current marketing mix of promotional inputs to doctors such as samples, gifts, sponsorship for doctors meets and other traditional tools will continue at the same time emerging media like internet, health magazines, medical books are in introductory stage in India but may prove to be effective media vehicles for dispersing information on health issues, treatment options and drug information.

The researcher also suggests reveals that the doctors are worried about the Direct to consumer pharmaceutical advertising as it will educate and make aware about the drugs and secondly looking at the success of OTC brands like Crocin, ENO, Revital etc in the OTC marketing, doctors were found to be worried on the fact that the Direct to consumer pharmaceutical advertising will replace doctors .which is not possible at this moment. The present research also suggests to bring out a rational marketing strategy on Direct to consumer pharmaceutical advertising which will be useful to public at large who cannot afford to visit Doctor and those whose don’t have time and rely on self medication and also benefit the manufacturer by increasing sales of the products, secondly it will improve profitability of brands, increase market size and reviving the mature brands those otherwise would have died.

Dr. Gulshan Gidwani(2003)\(^7\) in his thesis says that a sea change is seen globally and Indian Pharmaceuticals used to look into new marketing strategies as a part from Traditional relationship marketing analysis also showed on the commutates impact of Government restrictions on branding of marketing and drugs. He further states “the marketing manager often fails a lower choice of strategies as compared to the consumer health and OTC product as these products can be advertised and promoted legally. Role of strategy is seen to more crucial with changing marketing landscape in India. The researcher had also analyzed the importance of marketing management of OTC healthcare products greater availability of OTC Products and increasing interest of companies in building brand has gained huge importance in these days. Pharmaceutical
companies have become more conscious on product quality and promoting these products as if they are fast moving consumer goods. Pharmaceutical companies are trying to increase brand equity in the market through different marketing strategies. He further states that urban markets are more fertile than rural market for the sale of branded OTC products as its main cause is education level in urban market, advertisements on different media. Role of distributor and Retailers on pushing the specific brands of OTC products for higher margins. Finally he concludes that establishing a brand is not a day dream it’s a process, branding of OTC drugs will increase the sale. Creating a Brand is a strategic marketing activity and it plays an important role in making a product successful. Hence the study on marketing strategies becomes important to understand the perception of brand. So the researcher has chosen the topic marketing strategies for OTC products

Dr.Deepak Udgaonkar (1998) in his thesis” A study of problems of intermediate channel in Sangli Districts.” States that lack of adequate resources to maintain effective logistic system and distribution networks had increased the problems for chemists, patients and marketing executives of a pharmaceutical company. Retailers of pharmaceutical products had suffered losses like leakages, spoilages, date of expiry of products if not replaced well in time by concerned whole seller of pharmaceutical products. The researcher also states that majority of doctors have financial interest in form of cash of kind for prescribing a particular products manufactured by a specific company secondly the researcher revealed by the researcher that Medical Representatives play a role of mediator or link in between the prescribing doctors and pharmaceutical companies. The researcher also found that most of well qualified and renowned doctors keep medical Representatives detained for long time in hospitals for a single call. The researcher also cautions about the growing tendency of consumers to self medicate in minor ailments. Which is increasing demand of OTC drugs the roles of chemists are changed from a just chemists to a counseling chemists in minor ailments as the consumer are by-passing doctors in minor ailments. The retail elements shops are becoming more of OTC and grocery shops. As per his reference the success or failure of the pharmacy company providing even OTC drugs is dependent upon intermediates who constituent the channel of distribution of products. The researcher also states that less number of authorized chemists and more & more drugs Switching Rx to OTC may force retail grocery and general shops as modern trade for OTC marketing. He sincerely states that the Pharmaceutical industry has to play a vital role in the successful implementation of programmes like – health for all. So the study on marketing strategies of OTC products becomes important as these drugs will be available with non-chemist.

Prof.Satwinder Sing (1983) in his PhD thesis titled” Co- operation & Pharmaceutical industries.” Proper role and involvement of pharmacist in medicine management and overall healthcare programme, therefore, becomes very crucial. Wide range of drugs and healthcare products need to be properly stored and distributed by a qualified pharmacist so that they can be appropriately used by a patient. In the emerging scenario, it is logical that society would be happy to rely upon pharmacist to enhance the quality of drug therapy by identifying inappropriate prescribing, pharmaceutical delivery, patient compliance, patient idiosyncrasy and appropriate monitoring of drug therapy. However,
pharmacist will have to develop their pharmaceutical expertise and facilities in order to deliver high-tech and individually-tailored medicines in the primary care settings. Hence, when the individually modified medication arises. The role of OTC Drugs cannot be ignored. Thus my study on marketing strategies on OTC Products will have its own importance as this area remains unexplored in management studies. The research student had analyzed the importance of branded OTC healthcare products. Greater availability of OTC Products and increasing interest of companies in building brand has gained huge importance in these days. Parma companies have become more conscious on product quality and promoting these products as if they are fast moving consumer goods. Parma companies are trying to increase brand equity in the market through different marketing strategies.

The researcher further states that urban markets are more fertile than rural market for the sale of branded OTC products as its main cause is education level in urban market, advertisements on different media. Role of distributor and Retailers on pushing the specific brands of OTC products for higher margins. Finally she concludes that establishing a brand is not a dream it’s a process, branding of OTC drugs will increase the sale. Creating a Brand is a strategic marketing activity and it plays an important role in making a product successful. Hence the study on marketing strategies becomes important to understand the perception of brand. So the researcher has chosen the topic marketing strategies for OTC products.

2.4 REVIEW OF RESEARCH ARTICLES

Vijay Bhangle (2007) In his research paper on “OTC marketing in India” this study was conducted in different part of Mumbai and the sampling unit were Doctors, retailers and Consumers above 18 years as per convenience to determine the extent of self medication and consumer attitudes towards OTC medicines. OTC drugs means legally allowed to be sold “Over the Control” drugs i.e. without prescription of a registered medical practitioner; in India prescription drugs falling under two (2) schedules of drugs and cosmetics rules 1945. Schedule drugs under schedule X.

The researcher had sketched profile and Key categories of OTC potential would be – Vitamins and Minerals, Cough and cold, Gastro intestinal, Dermatological Digestive, Antacids, Anti inflammatory, cold rubs & analgesics balms/ creams, vitamins, tonics, health supplements (especially herbals and ayurvedic registered). Skin treatment, cold tablets glucose powders, cough liquids throat lozenges Band aids, Baby gripe water. OTC medicines which can be seen, advertised on television in India.

The study reveals that marketing of OTC drugs is changing as the demand for OTC drugs among Doctors and consumers is increasing. This is a healthy indication of growing demand for more OTC categories and foundation for self medication revolution in minor ailments.

The study also throws light on attitude of Doctors towards various aspects of OTC marketing. Thus it can be said that OTC marketing is accepted by health care system.

Dr. R.B. Smarta (2005) in his research article on “Marketing strategies in Asia pacific Region” has analyzed the potential market in Asia Pacific for OTC drugs. The growth drivers for OTC drugs are growing and overall environment in Asia is improving, HealthCare infrastructure is improving, Life styles are changing giving rise to new medical needs. Marketing strategy are crafted keeping in view customer of Asia and priced low.
The researcher had analyzed the situation in Asian countries so that OTC products are marketed freely in Asia. While the focus on customer is important in the pharmacy business which contains 3 segments doctors, Pharmacists and the patient. The marketing landscape is changing very fast and the competition is becoming very several.

New marketing strategies have to be developed in Asian country. Apart from this the researcher had pointed out regional strategic challenges which can be rooted out if proper and rational strategies are build on regional and national level basis. According the researcher the challenges were lack of harmonization of regulatory practices, rational lowered tariffs and duties and Pricing policies should be development to avoid disruption in smooth flow of medicines from place to another and finally uniform taxation policy throughout India to avoid confusion in pricing.

R.K. Srivastava (2007) in his research article on consumers’ attitudes towards Pharmaceutical OTC Products. The researcher had conducted a survey with sample size 677 and 125 doctors in major Nagpur, Mumbai and Chennai to find out consumers’ attitudes towards Pharmaceutical OTC Product . the researcher had sketched the profile of Indian ethical pharmaceuticals Multinational pharmacy companies control 35% of market and the physicians are very important as earlier but today new marketing strategies are directed towards Consumers, Newspaper advertisements and television advertisements are seen. For OTC segment the situation are different. There are many prominent OTC drugs which have played important role and created history. Some brands like Crocin, Anacin, Corex, Benadryl and Dcold. Indian OTC Pharmaceuticals has seen mammoth’s growth of 8.6% (2007 4th month). The researcher had cited few examples like; Glaxo SmithKline made Crocin & Pfizer made Benadryl & Gelusil as OTC products showing rock of speed growth in sales Ranbaxy made Revital as an OTC two years back. The researcher also investigated the major reasons for purchasing OTC product like efficacy of products, brand names and pricing play important role on purchase behavior.advertisements affects consumer behaviors in building brand equity as most of the consumers don’t know the parent company of the brand consumed.

The study also revealed that consumer prefers OTC products as a substitute to Rx products and doctors irrespective of their age and specialty do not like to prescribe OCT drugs. The article finally states that pharmacy companies thus have a good scope to grow in OTC category.

The researcher also suggests that pharmaceutical companies should understand that the patents of specific drug is expired can expire the market the best strategy would be to switch the prescription drug to OTC (Over-the-counter) status which will make the drugs available without doctor’s prescription.

Mayyada Wazaify & et al (2005) in their research article on “Societal Perspective on OTC medicines family practice” the research was carried out to know the public opinion and prescriptions of OTC drugs and their misuse and abuse of such preparations..the research revealed that majority of consumers visited community pharmacists at least once in a month and majority of them followed the direction on the products the general public in the research area Ireland were found to be highly aware of the abuse of potential OTC drugs. It was also found that the participant who had used inappropriate OTC drugs had encountered cases of OTC abuse. The study had also revealed that three quarter of the surveyed were found to be regular user of community pharmacies services for self medication, OTC products are been increasingly used for self medications and after using these products few have encountered OTC drugs abuse, majority of the surveyed
participant’s visits every month. The views of OTC medicines in terms of safety, potency & effectiveness/ knowledge and opinion of misuse of OTC medicines were also noted. It also critically examines the abuse encountered cases of OTC abuse. The role of Pharmacists in management of OTC drugs use. The challenge in controlling the problem of OTC misuse and abuse is to achieve the necessary high level of safety. The study also suggested that, education, safe and effective use of such medicines can be promoted. Thus it can be said that, the challenge is to control the misuse of the drugs and avoid the abuse. The Marketers and Government can monitor usage of OTC products by asking the chemist to maintain the sale of OTC drugs, Patients data and prohibition of hopping from one chemists and the another .secondly warning through rules and orders to chemist about the quantities of OTC products that people could purchase.

Colin Bradley and Co-workers (1998) 14 in their research paper on “Patient’s attitude to over the counter drugs & possible professional response to self medications”. The paper critically examines the research about patients’ attitude to their doctors recommending OTC drugs. It was revealed that patients are more ready for their doctors to make enquires about their self medication behavior and influencing their self medication behavior .secondly the patients quietly accepted the pharmacists after doctors prescription .it was found that the doctors recommending OTC drugs were well accepted by patients and found to be receptive with the idea of OTC medication. The study also revealed that patients who were already using OTC drugs also accepted the prescription and didn’t ignored the reason might be common anxiety among doctor and patients to know more about self-medication. The research also focuses on the small but significant number of herbal users or homeopathic remedies.

It was revealed that female are more comfortable with homeopathy and herbal medicines than men. The majority of patients found to be agreed that chemists is the best source of information, advise about minor medical problems. Chemist are found advising on prescription drugs and many a times patients were unable to afford the medical cost hence switched to OTC drugs which were less expensive and easily available.

Suresh Madhavan (1994) 15 in the research paper analyzes the behavior of physicians in presenting OTC products. The authors had examined the Influence of physicians attitudes the Rx to OTC switching of drug products, consumer self medication and the role of physicians attitudes in influencing the patients to such from Rx to OTC felt more expenses of physic and had significantly less favorable attitudes toward Rx to OTC switching & consumer self medication. The overall goal of this exploratory study was to assess physicians' attitudes toward the prescription-to-nonprescription (Rx-to-OX) switching of drug products, consumer self-medication, and prescribing of switched products; to assess physicians' perceptions of the impact of switching on patient visits, on practice, and on existing prescribing behavior; and to determine the differences in physicians' attitudes and perceptions on the basis of selected demographic, practice, and prescribing characteristics. Additionally, the role of physicians' attitudes in influencing their overall judgment was assessed. Data were collected from 181 randomly selected West Virginia physicians using a mail questionnaire. Consumer self-medication and prescribing of switched drug products. Generally family practitioner were more inclined to stop prescribing a drug product if it was switched from Rx-to OTC than specialist physicians. Physicians who see a large number of patients per day or write a large number of prescriptions per day are also more likely to stop prescribing a drug product if it is switched than physicians who see a small number of patients per day or write a small
number of prescriptions per day. Non-prescribers of OTC and Rx-to-OTC switched products had significantly less favorable attitudes toward Rx-to-OTC switching of drug products, consumer self-medication, and prescribing of switched drug products. More experienced physicians had less favorable attitudes toward Rx-to-OTC switching and consumer self-medication and were less likely to prescribe switched drug products. About 35% of the respondents either favored or opposed OTC status for all 3 potential switch candidates. Thus it was found that, analysis indicated that attitudinal factors best between physicians who favored and physicians who opposed OTC status for the three potential switch candidates

Donald L and etal (1994) in their research paper on “An assessment of consumer purchasing behavior for private label Vs Brand name OTC products in chain pharmacies.” The consumers purchase private label & branded OTC products from the pharmacies. The study also analyzed the consumers purchase private label consumers perceives that private label products are quality products the fact is branded products cost more than the private labels, Branding of OTC products has increased the cost of the product. The purpose of this study was to determine consumer purchasing behavior for 38 private-label and brand-name over-the-counter products. Questionnaires were administered to 525 consumers at 3 chain pharmacies in different socioeconomic areas. Overall, 68.7% of the respondents indicated purchase of the private-label product, and 80.5% indicated that the quality of private-label and brand-name products is equivalent. The results showed a possible association between perceived product quality and purchase decision. Results also showed that all of the private-label products could withstand a price increase before a majority of respondents would switch to the brand-name product. Sixty-four percent of the respondents indicated that they would change their purchase decision based on the recommendation of a pharmacist. The pharmacist’s plays important role in promoting the OTC drugs either private labeled or branded OTC drugs. Consumers are ready to change their brands on the recommendation of the pharmacists.

8. Tracy porter & Mickey Smith (1994) in a research paper on” College student’s perceptions of OTC information source characteristics” critically examined the college students. College students' perceptions of characteristics of sources of information about over-the-counter medications were obtained, and the relationship between information source characteristics and the likelihood to use that source for information was examined. A survey was administered to a sample of 789 college students at 16 colleges and universities nationwide. Students identified formal sources-physicians and pharmacists-as the most accurate, most expensive, most time-consuming, and least convenient source of OTC information. Informal sources-friends, family, and TV advertisements-were rated less accurate but better in convenience, expense, and time consumed scores. Students do take OTC products & the formal sources of getting OTC products Information serve is pharmacists and physician as the most accurate, expensive source of Information. The informal sources through which patients get information very early are TV, News paper, family, friends and advertisements. Consumer purchases OTC products on basis of information provided or thrown by companies in the form of promotions. In an American survey conducted on the information sources used for OTC drugs were accounted as TV Advertisements and Doctors. It was also revealed advertising also help consumer awareness of OTC products. Advertising also help the consumers to understand what OTC Drugs are available for different illness. Physicians and pharmacists were also
found to main source for information about minor illness and OTC remedies, promotion and labeling of products also play important role.

Patricia Harrington (2008) in her research paper on “Analysis of the Movement of Prescription Drugs to Over-the-Counter Status”, the researcher ad critically examined the prescription-to-OTC switch movement is complex and multifactorial. Forces impacting on the movement of prescription drugs to OTC status include the market expansion motives of the pharmaceutical industry, a national trend toward deregulation, the growth of the self-help movement among consumers, and cost-containment efforts by the health care industry. Many products will be proposed for such changes of status from Rx to OTC on a very frequent basis by those who have a strong self-interest in the change. The volume of prescription-to-OTC switches will continue to grow in the years to come in many parts of the world specially in country like US, where consumers are self driven in taking there health charge.

Cecilia M. Acocella (2005) in her research article titled “on prescription Drugs use among University students. The research had as critically examined the use of OTC drugs among university students and their behavior. The usage of drugs like painkillers, relievers irrespective to brand or company .the sale of such drugs have seen huge growth but at the same time the writer warns the effect of misusing these kinds of drugs without consulting the doctor or reading the label carefully among the university students. The most commonly used items included remedies for cough and cold, antipyretics and analgesics. Topical preparations and herbal medicines were also frequently consumed. Self-medication items were mostly obtained from home medicine cabinets and pharmacy shops (not necessarily staffed by registered pharmacists) and they also relied heavily on family members and previous illness experience for information on the medications they took. The healthcare professionals only played a minor role in the provision of drug information. Nevertheless, the concept of self-medication is well-established among these university students as they recognized that minor illness could be cared for without seeing a doctor. Thus it was found that Healthcare professionals should assume more active roles in the provision of drug information and counseling so that a good self-care programme could be established.

Douglas Ws and Co- worker (2008) in their paper “the role of advertising in communication New OTC Drugs indication” Advertising is an effective means to communicate new products and new benefits to the consumer, a part of communication plan. OTC Product advertisement educates the consumer hence the advertisement calls for more clarity on the essential labeling information. and finally the advertisements must to truthful, accurate and not misleading. The study revealed that all promotional pieces and ads to be used when a new drug is marketed must first be approved by the FDA before marketing begins—to ensure that the statements being made are consistent with those in the official labeling. After the introduction of a new drug has been completed, copies of all subsequent ads and promotional pieces must be sent to the FDA at the time of their first use, too, but they do not have to be preapproved. The FDA reviews ads, brochures, direct-mail pieces, and sales aids to ensure that a "fair balance" has been maintained in presenting both the benefits and risks of a medication. The study suggests, the FDA directed its attention towards scientific conferences and other medical meetings at which information about new drugs, or new indications for drugs, are presented. This ensures that they are not just promotional programs for a single drug. In no other industry
are advertising and promotion required to meet such strict standards. Finally the study suggest to bring out advertisements which claims are substantiated and are not misleading

**Pascale Allotey and co-workers (2004)** in their research paper on “Over-the-Counter Medication among Australian Children”. The study was carried to identify the patterns of use of over-the-counter (OTC) medications among children. For this study was used as a qualitative design, within-depth interviews of 40 parents with children <5 years of age. This study also brings into sharp focus the largely unexplored area of the use of OTC medications as a form of social medication for the control and maintenance of “good” behavior among children. One was the administration of OTC medications as a form of “social medication,” to give parents control over children’s behavior that they perceived as fractious and irritating. A related theme was the use of OTC medications to reduce the inconvenience to the parents of having a sick child, again giving parents greater control and better time-management abilities. Finally, OTC drugs used have almost amazing properties in calming, sedating, and lifting the mood of children. The use of OTC medications for the treatment of minor ailments among children is widespread, despite the lack of evidence of efficacy of the most commonly used medications and the potential for toxicity. With the increasing propensity to look to medication as a means of supporting changing lifestyles, there is an urgent need to review the prevalence and effects of social medication. The study was small and qualitative, and the sampling strategy permits no inferences to be drawn about the broader population. Nevertheless, the study highlights the need for a larger, population-based survey regarding some of the issues identified by the mothers, to determine not only the extent to which these practices occur but also the distribution and consequences of their occurrence. Thus it was concluded that use of OTC medications for the treatment of minor ailments among children is widespread, despite the lack of evidence of efficacy of the most commonly used medications and the potential for toxicity. With the increasing tendency to look to medication as a means of supporting changing lifestyles, there is an urgent need to review the popularity and effects of social medication using OTC drugs in Indian environment also. The present research is an attempt to study the OTC drug medication and social issues also.

**Sheth A; Khurana R; Khurana V(2008.)** The growing popularity and availability of over-the-counter (OTC) health products, including vitamins, raises serious concern about vitamin toxicity. The researcher had analyzed a case of cirrhosis in a patient with habitual daily ingestion of an OTC dietary supplement that contained 13,000 mcg vitamin A and was associated with marked clinical improvement after discontinuation. This case highlights the potential for liver damage that may be associated with long-term intake of OTC vitamin supplements, and indicates the need for medical supervision of such products. Specifically all those OTC products and vitamins available easily at the counter without any supervision, pharmacists had to play an important role in counseling the patients on dangers associated. This study had made no attempt to assess the patients perspective in context with the role played by pharmacist’s working in government hospitals. The role of Pharmacists in giving advice to the patient in usage of OTC drugs is very crucial. The quality linked to an ideal Pharmacists can be summed up as being assertive, being able to reach at patient, assess their hesitations and promptly offer solution. A Pharmacists in order to save his professional image should play a proactive role in becoming effective & indispensable part of health care. A Pharmacist should
always equip with appropriate knowledge in order to render efficient and outstanding pharmaceutical health care.

Dineshkumar B and etal (1995) in their research paper on “Profile of drug use in urban and rural India” In the present study, a profile of 1769 doctors' prescriptions and 763 self-orders were monitored at pharmacy outlets in the twin cities of Hyderabad and Secunderabad and 4 rural areas of Andhra Pradesh with the aim of identifying urban and rural differences, if any, in the self-medication rate, prescription costs, types of drugs purchased and factors influencing self-medication. Self-medication, expressed as the percentage of the total population that self-medicates, was found to be high in urban areas (37%) compared with rural areas (17%), and the majority of the over-the-counter sales were for prescription-only drugs, the study reveals that majority of physician’s prescriptions were incomplete with respect to the diagnosis and dosage assign. The cost accrued for prescribed drugs by physicians was twofold than the cost drugs sold OTC. The Urban elite considered that all the prescribed drugs were not necessary for these present disease. Nutritional products, analgesics, antipyretics and anti-inflammatory and antibiotics constituted a high proportion of prescribed OTC drugs by doctor’s. The author further states there is need of comprehension measures like information, training at all level of drug delivery system to improve and influence self medication.

Greenhalgh T (1998) in his research paper on “Drug prescription and self medication in India-a survey” has analyzed the prescribing and dispensing of drugs in India. Large number of doctors in private clinics, many unwanted, hidden class of drugs are given which are of no-use for the patients. Drugs banned in west remain popular in India. Tonics and nutritional supplements are prescribed which increases the OTC Drugs bill. The researcher also concludes that the rational drug policy will be useless unless doctors and pharmacists are educated and trained to reduce the drug prescription which only serves commercial purpose of pharmaceutical companies, Doctors and Pharmacists only. The study also reveals that self medication in minor ailments using OTC drugs will lower down the expense and unwanted prescription list.

Vinay R Kamat and Mark Nichte (1998) in their research paper on “Pharmacies, self medication and pharmaceutical marketing in Bombay-India.” The role played by Pharmacists in fostering self medication has been examined by the researcher. Pharmacists acts like agents encouraging self medication among public life though the fact is pharmacists lacks training, pharmacy attendants engage in prescribing Medicines in Bombay. The symbiotic mechanism of pharmaceutical companies, Doctors, medical representatives, and drug distribution system, retailer fostering prescription practice, pharmacy over counter pushing of drugs for only economic relations needs to be more closely screened.

R.William and Soller (1996) in their research paper on “Evolution of self care with over the counter medications” the study focuses on Self care with home remedies that had evolved from ages. Prescription to OTC switch has become a modern era strategy. Self care has made consumers more self reliant towards Healthcare thus reducing cost on healthcare. Companies expending their OTC Product lines taking into the consideration of self medication attitude among patients. Proactive regulatory decisions make it easy to sale; promote OTC drugs like FMCG products.
Erica D Brownfield and co-workers (2007) in their research article on “Direct to consumer drug advertisement on television network. An Exploration of quantity, frequency and placement” There is a rapidly growing practice within the pharmaceutical industry of advertising prescription products directly to the general public through media, such as television, radio, newspapers, and popular magazines. Proponents of direct-to-consumer advertising of prescription drugs have asserted that advertising is a source of useful information for the patient. However, it is the position of the Academy that patient education regarding prescription drugs is provided best by the physician within the context of patient care and not through advertising that is designed primarily to promote the sale and consumption of a specific product. Such advertising contributes little, if anything, to the quality of health care while posing multiple problems that may be counterproductive to the provision of optimal pharmacotherapy for pediatric patients. 

There is a huge opposition to direct-to-consumer advertising of prescription drugs from its long tradition of advocacy for children and young people, along with a concern regarding the potential negative impact of such advertising on the health care of children and adolescents. The Study objects to consumer advertising of specific prescription products, Prescription drugs are unique in the marketplace in that they are selected for use by the physician rather than by the consumer. They are designated by law to be used within the patient-physician relationship for the protection and welfare of the patient. In choosing a therapeutic agent for a particular patient's illness, a physician takes into consideration a large amount of complex factors, including the, medical history, previous medication intolerances, adverse drug reactions, chemical dependency, The experience in Canada provides a cautionary tale for governments in India who is attempting to juggle industry demands for greater ability to ‘inform’ the public about their medicines with public, professional and parliamentary reluctance to introduce ‘US-style’ prescription drug advertising.

Hollis Ashman and Et.al (2008) in their research paper on” Consumers choice for OTC drugs & supplements in the health care arena, Approaches to a macro database across topics “had critically examined haw consumer respond to certain area s of OTC health care from simple physical examination as a service to medical shampoo as a products. Information available on internet which changes the mind, behavior that transcends individual OTC product groups. There are separate frameworks in the consumers’ minds on self-medication as they have choice over OTC medicine. Consumers mind is the source of material to be database. Marketers also refuse to move forward without information about the market place from these data base. The paper also investigates that using consumer attitude as data base in limited to general trend studies. Creating a cross sectional & longitudinal data base to understand the algebra of the consumer minds was necessary & which was difficult.

Anna Birna Almarsdottir(2000) in her research paper” Over-the-counter use in Iceland: the impact of increased access” The main objective of this study was to test the assumption that liberalizing community pharmacy ownership in Iceland would lead to increased irrational use of over-the-counter pain reliever More than 50% all medicines prescribed dispensed or sold inappropriately. 50% of patients fail to take them correctly. On the other hand, about one-third of the world population lacks access to essential medicines. Treatment with medicines is one of the most cost-effective medical interventions known and the proportion of national health budget spent on medicines
ranges between 10% and 20% in developed countries and between 20 and 40% in
developing countries. Thus, it is extremely serious that so much medicine is being used in
an inappropriate and irrational way. Common types of irrational use of medicine are the
use of too many medicines per patient, inappropriate use of antibiotics, often in
inadequate dosage, for viral infections, Over-use of injections when oral formulations
would be more appropriate. Failure to prescribe in accordance with clinical guidelines,
inappropriate self-medication, often of prescription-only medicines. Communication
between professionals and consumers is fundamental to the improvement of rational use
of medicines by consumers. Professionals should provide the following information to
the consumers: the name of the medicine, the purpose for which the medicine is being
taken, dose, frequency of use, and duration of use. The prescribed and dispensed
medicines should also be properly labeled indicating the above information. The shortage
of qualified health personnel in public health facilities has resulted in inadequate labeling
of medications, and in insufficient time spent by them to inform the consumers on how to
take the medicine. Also important are the possible drug and food interactions that might
occur after taking the medicines.

An increasing number of drugs are sold directly to the consumers without a prescription
from pharmacies and from non-pharmacies such as supermarkets and gas stations the
influence of the company towards prescribing its product especially when new product
introduced into the market. In future to protect patients from this serious and widespread
public health problem. Nonprescription (over-the-counter) drugs permit patients to treat a
wide range of minor, usually self-limiting, problems and may be helpful before
professional medical assistance is sought or when it is not immediately available.
While their misuse may at times create or compound medical problems, most people
perceive OTC drugs as safe and effective in their limited role. In fact, however, the
evidence supporting safety and effectiveness of most OTC products has never been
subjected to critical review. The principal reason for this is that most OTC products are
made of ingredients marketed long before the modern requirements of the food, drug and
cosmetic act were promulgated.

Andersen A; Holstein BE; Hansen EH (2006)30 in their research article on’ is medicine
use in adolescence risk behavior? Cross-sectional survey of school-aged children from 11
to 15” the researcher had seriously warn the adolescence to change their eating ,
drinking & smoking habits as to get rid-off headache and stomach pains. It was
revealed in the study that school going kids approach pharmacists for OTC Medicines.
Secondly it was found that OTC medicines which are advertised everywhere through the
medias are the most wanted drugs for children of the researched age group and
pharmacists are ready to help the patients in such cases ,but the use of OTC drugs as life
style drug can lead to bigger risk in connection with habits.

Barat I, Andersen F, Damsgaard EM. (2000)31 in their research paper on “The
consumption of drugs by 75-year-old individuals living in their own homes.” The
research paper states that OTC drugs are consumed by all age groups including 75 year
old individuals. The use of OTC drugs almost in all 75 years old persons increases the
risk drug related risks. The discrepancy between doctors and the patient’s medications
and actual intake of drugs on pharmacist advice or after watching Television
advertisements increases risk.
It was revealed that old age individuals are more OTC use in minor ailments as compared to prescription. The frequency of consuming OTC drugs without asking chemists is causing side effects as their immunity to cope up the strength of OTC drugs is found to be low. Thus the study suggests community pharmacist and active rules to avoid excess medication among the elder patients.

**Black R.A. Hill D.A (2003)***

in their research paper on “Over-the-counter medications in pregnancy” the study reveals that, OTC Medication in pregnancy is commonly used as most of the OTC drugs have excellent safety profile, but some have proved fatal during pregnancy. Many gynecologists prescribe OTC drugs for minor ailments but the benefits of OTC drug should not damage the fetus. A common concern about the care of pregnant women involves the use of over-the-counter (OTC) medications. Nonprescription drugs account for about 60 percent of medications used in the United States, and more than 80 percent of pregnant women take OTC or prescription drugs during pregnancy. Of the new OTC drugs marketed between 1975 and 1994, 30 percent were previously prescription medications. Physicians should educate pregnant patients about the harmful effects of smoking to themselves and the developing fetus, and help these patients develop a plan for smoking cessation.

The safety of nicotine replacement products in pregnancy has not been adequately studied. However, smoking is likely to be more harmful than nicotine replacement therapy, particularly because cigarette smoke contains more than 3,000 different chemicals that can potentially harm humans, and one of the main components of cigarette smoke is carbon monoxide, a known fetal toxin.

Therefore, it is reasonable to consider the use of nicotine replacement products in patients who cannot maintain smoking abstinence without pharmacologic intervention.

**Burak, L. J., & Damico, A. (2000)***

in their research paper on” Effects of direct-to-consumer advertising of pharmaceutical products on college students” has analyzed the impact of promotions activities on students. The study describes college and university students' use of widely advertised pharmaceutical products. It was found that Four hundred seventy-one students from three institutions addressed the use of advertised medications, attention to magazine ads for medications, communications with physicians about medications; Results indicated that the majority of the students used at least one of the advertised products. Most students did not discuss the pharmaceutical products with their physicians or discuss the conditions for which they reported they were taking the drugs College student often use advertised OTC Pharmaceutical Products, their attention to magazine advertisements for medication is noticeable. Majority of students take advertised OTC drugs without discussing to the doctor. Advertisement play important role for promoting OTC products among college students their life style is bit of glamorous.

**Byrne A, Somergy(2006)** - States Overdose of OTC drugs if taken needs careful attention otherwise it may cause dangerous effects as these products does not require doctors prescription or advise. The matter of concern is the labeling of directing a how to use the drug matters a lot. Excess use of OTC drugs without reading the dosage suggested will have fatal effects. So the company should clearly mention on the label & consumers should read it carefully. The growing popularity and availability of over-the-counter (OTC) health products, including vitamins, raises serious concern about vitamin toxicity.
Burt A; Annest JL; Ballesteros (2006)\textsuperscript{35} in their research paper on “Nonfatal, Unintentional medication exposures among young children” the study investigated children age 4 and under were treated in hospital emergency rooms for unintentional exposure to prescription and over-the-counter medications. Most of these occurred in the home. These children were nearly four times as likely to hospitalized or transferred for specialized care as other children in the same age group, treated for all unintentional causes of injury (9.7% versus 2.5%). Over-the-counter preparations represented 42% and prescription medications 39%. The most common medications were central nervous system agents (e.g. acetaminophen). Those most commonly involved in hospital admissions were calcium-channel-blocking, and antidepressant and mood-stabilizing agents. The study reveals the tendency of families to make first Aid box full of OTC drugs is increasing. A lot of stock is maintained at home which promotes the act of OTC consumption for every minor pains which may result into hospitalization. Patents attitude towards Advertisements as television, newspapers & health magazine has forced to take reins of life in their hands via self medication using OTC products such as growth supplements & calcium supplements.

Hollis Ashman and etal (2008)\textsuperscript{36} in their research work on “Consumer choice for over-the-counter drugs and supplements in the healthcare arena: Approaches to a macro-database across topics” the study was carried out to understand how consumers respond to eight areas of over-the-counter (OTC) healthcare, ranging from simple physical examinations as a service to medicinal shampoo as a product. The objective was to understand how the consumer processes information about healthcare such as the information that is currently available on the internet, and whether there exists a higher order set of behaviors that transcend individual OTC product groups. In today's economy, the consumer is bombarded with choice. They can find many different ways to deal with pain for example, analgesic tablets and creams. The study revealed that, many companies o understand not only the consumer's mind, but also what the true competitive set of products is as the consumer experiences them. As the movement towards ‘direct to consumer’ (DTC) gains speed the consumer will become increasingly important, even in the choice of traditionally prescription (RX) drugs. Many drug companies today focus a great deal of effort on advertising. The study comprises a combination of self-profiling to understand the mind of the consumer, and conjoint analysis to understand the choice of features and communications.

The study suggests a division of consumers into three segments: those who want a quick fix, those who want a statement of the benefit to them and those who want a detailed explanation of how and why the product works. This study investigated ad maintained the database on self-medication at the macro level As consumers are often times self-diagnosing and self-medicating, understanding what messages are most important will help the consumer to understand how to gain relief from their ailments and what other factors are important.

Desai S and etal (2006)\textsuperscript{37} in their research case work on “Chronic addiction to dextromethorphan cough syrup “the study had shown Serious drug abuse and addiction related to dextromethorphan-containing cough preparations has been a problem in the United States since the 1950s, but few physicians are aware of it. The study also warns the Physicians to be alert to the type of substances and quantities used and misused by patients in obtaining a thorough routine history of over-the-counter medication use. Despite the availability of a substantial number of case reports in specialty journals, there
are almost no reports in the primary care literature of chronic addiction. The study reveals the difficulties in making an appropriate diagnosis and in obtaining effective help for the patient. Similar cases were observed in Indian market. The present study on OTC marketing will reveal the reasons of self medication and addiction related issues the study critically narrates that chronic addiction of OTC products like cough syrup has been as serious problem in India & US. As the OTC product are promoted through television advertisement like any other FMCG Product. The consumption is high Physicians should be aware of the Patients routine history of OTC drugs many a times patients demand a specific brand resulting into a chronic addition.

**Fleming GF and co-workers (2004)**[^38] in their research work on “Development of a community pharmacy-based model to identify and treat OTC drug abuse/misuse” The aim of this study was to develop a harm-minimization model for the identification and treatment of over-the-counter (OTC) drug abuse/misuse by community pharmacists. The study revealed that a community based model will help in minimizing the overdose of OTC products. The model in consultation with a range of healthcare practitioners, psychologist specializing in communication skills were allowed to develop communication aspects of the model. A comprehensive manual detailing the model was prepared; the model is designed to be used by community pharmacists in conjunction with other healthcare professionals. It focuses on the abuse/misuse OTC and can be broadly divided into three phases, namely: patient identification and recruitment, treatment/referrals and data collection/outcome measurement. Client identification is via record-keeping which is implemented alongside an information campaign promoting safe use of OTC medicines. Once identified, the pharmacist aims to recruit clients using the developed communication strategies. Treatment depends on whether the problem is misuse or abuse and on the product the study revealed that using the model of community pharmacists, consumers agreed to stop using the product and/or to try safer alternatives. As expected, some sales had to be refused, as consumer was unwilling to accept the pharmacist's intervention.

Thus it was concluded that the structured attempt by community pharmacists in the UK to address the abuse/misuse of OTC medication. Similar models can fit in Indian environment too. A pilot study suggested the model of developing a community pharmacist in UK to address the misuse of OTC Medicines & also use of OTC Medication. The study recommended that the ban on sale of some products which the client refused as the customer was unwilling to accept the intervention of Pharmacists.

**Lo A; Shalansky and Etal (2003)**[^39] in their research paper on” Patient characteristics associated with nonprescription drug use in intentional overdose” the study investigated that Over-the-counter (OTC) medications remain freely available to suicidal patients, despite their potential harmfulness and common use in suicide. The study's main objective was to identify patient characteristics, particularly psychiatric diagnosis associated with the use of OTC medications in intentional overdose. The study was carried out to identify potential risk markers for OTC medication use, and logistic regression was performed using these variables. It was found that the variables age, sex, and concurrent psychiatric diagnoses were controlled; use of OTC medications in overdose was significantly lower in patients with a diagnosis of substance abuse and in those who possessed prescription medications at the time of OTC overdose. Most patients in this group (82%) had at qualities of suicide. Although not statistically significant, younger patients appeared more likely to choose OTC medications for overdose. Thus it

[^38]: Fleming GF and co-workers (2004)
[^39]: Lo A; Shalansky and Etal (2003)
was found that Suicide-prone patients with a diagnosis of substance abuse and who possess prescription medications are unlikely to use OTC medications in overdose. This reveals the relatively small proportion of patients whom doctors should consider to be at greater risk for attempting suicide when using OTC medication. The study also reveals that as OTC Medicines remain freely available to the suicidal patients, intentional overdoses of OTC Medicines cause for psychiatric diagnosis, younger patients appeared more likely to choose OTC Medication for addiction in many countries. Prescription drugs & banned drugs are also available as OTC drugs & can be purchased from retail counter resulting into intentional overdose & addiction.

Sanjeev Verma (2009) in his research study on “An empirical analysis of consumer’s attitude towards OTC health supplements in India”. The study revealed that the consumer attitude towards OTC health care is changing with a great speed. Consumer buying OTC products as soaps and biscuits the researcher found that an upsurge has been observed in India towards healthy and stress-free life. People are getting more inclined towards Over-The-Counter (OTC) purchase of health supplements. The segment is growing at the rate of 15%, which is twice the rate of growth for the entire pharmaceutical sector. Herein lays the greatest benefit for companies, since OTC promotion allows for free play in marketing and brand building, as in the Fast Moving Consumer Goods (FMCG) sector, with three times more consumer reach. But still the segmentation for health supplements is blurred. In this paper, an analysis has been made to identify the effect of demographics and pricing on the purchase of health supplements. This paper also highlights some of the important reasons for the purchase of OTC health supplements in India and satisfying factors for consumers.

Ramadan R and Co-workers (2003) in their research study on “Delphi survey of experts’ opinions on strategies used by community pharmacists to reduce over-the-counter drug misuse and addiction” the researcher had set some objective of this study to explore the views of experts within the fields of pharmacy and addiction on the value of current strategies and possible alternatives and to reach an agreement on best practice in the sale of over-the-counter (OTC) medicines which are liable to misuse. Gathered information by using Delphi technique data collected which resulted into issues of Non – Pharmacy outlets, internet sites & customer interests were seen to be conflicted. Community Pharmacists role was important in reducing OTC misuse irrespective of the margins, profits, gift the companies offered to the doctors & Pharmacists on achieving the sales target of OTC drugs. The study revealed that A Delphi technique was employed to gather data. The final questionnaires were constructed from the responses to the preceding questionnaires. Content analysis of the qualitative data was carried out at each stage. Statistical analyses of the influence of demographic factors, degree of shift in overall opinion between the first and second stages and degree of agreement between respondents at each stage were also conducted. It was found that consensus was reached on the strategies considered the most important and effective. Key areas include improving access to current information, improved staff training, addressing the issues of non-pharmacy outlets and Internet pharmacy sites. The study also expressed concern regarding the possible conflict between commercial and customer interests. Thus it was concluded that practical and realistic guidance for policy-makers and community pharmacists on the sale of OTC products is must secondly The effective implementation of these strategies can only be achieved with improved communication and coordination.
at local and national level bodies. An effective strategy would be communication at local, national level among Pharmacists, Govt. & Doctors, Patients & manufacturer.

Paninchukunnath, Ajith (2007)\textsuperscript{42} in his research paper on”OTC Drug Marketing – Global Trends and Indian Experiences” This paper takes a look at the OTC drug marketing at a global level with special focus on US and Indian markets. The study deals with changing consumer lifestyles. More and more consumers across the developed world and developing economies are becoming cautious about their health. Direct to consumer advertising is educating consumers across the nations in treating minor ailments by using OTC products. Marketing companies are crafting innovative marketing strategies to market their OTC products. This process is encouraging OTC marketing companies to advertise and promote the OTC products to the masses also. The study also found purchase of OTC products in Indian market is increasing with a high speed. This segment is seen more vibrant than earlier. Advertisements in any media is not restricted only to cold and pain but more and more categories in minor ailments are brought under the umbrella of OTC. The paper also narrates the scene in United States OTC drug market followed by Europe and India. Thus a holistic approach which Indian OTC drug marketing firms can adopt to create awareness about health and wellbeing is necessary and expected as marketing is fairly addressed in India but making products available and affordable remains the challenge in front of pharmaceutical companies. The researcher had made an attempt to bring out possible benefits and risks associated with OTC. Increased access to medicines in minor ailments without doctors supervision, improved education of consumers and cost of health maintenance gone down at the same time the study warns the consumer with risks like inaccurate diagnosis, delay in getting the required medication, drug efficacy and failure in following label instructions. Thus it was revealed that OTC drugs marketing are incomplete without educating the public on safe use of OTC.

Dr. Waris and co-workers, (2001)\textsuperscript{43} in their research work on” A study of over the counter medication use, among patients presenting to family physicians, at a teaching hospital in Karachi”. The study was a cross-sectional survey among the patients in Karachi who were found to be using OTC products under the supervision of family physician survey was carried by the researchers wherein a total of 393 patients were surveyed against a sample size estimated at 347. A questionnaire was developed and administered to collect information on the demographic profile and the “Over the Counter” medications use, among the respondents. It was found that Over the Counter medication use within the previous 6 months was found in 153 (39%) respondents. “Analgesics” were the most commonly used Over the Counter medication group among the respondents. Family friend and relatives were found to be most advised to self-medicate using OTC. It was also found that access to irrational use of OTC lead to abuse and misuse of OTC drugs were also reported and the reasons found were like save money by avoiding doctor’s consultation, and easy availability of medications in the open market. Thus it was revealed that patients will continue to depend on OTC drugs for self-care across the boundaries.

Bela Ganatraa, Vinoj Manningb, Suranjeen Prasad Pallipamulla (2005)\textsuperscript{44} in their research paper on part of a study on Availability of Medical Abortion Pills and the Role of Chemists: A Study from Bihar and Jharkhand, India., a survey of 209 chemists, in the Indian states of Bihar and Jharkhand in 2004. It found that only 34% of the interviewed
Chemists stocked abortion pills as OTC product, sales volumes were low and there was more demand for cheaper, often ineffective preparations for abortion. Men were more likely to buy contraceptive drugs than women. Chemists knew OTC product but less about dosage and side effects. Most sales appeared to be prescription driven, but some over-the-counter sales did occur, especially when ability to pay seemed high or the chemist knew the customer. Chemists need accurate information on the drugs they sell as abortifacients, encouragement to promote pregnancy tests, training in encouraging women to see a provider prior to purchase, and visual and written material to hand out. Better adherence to existing regulations for all prescription drugs is important, but the best course is to increase the availability of low-cost, safe abortion services at primary care level. The clinical safety, efficacy and acceptability of OTC product in the Indian context have been well studied, but little is known about how they are being used, who is using them, how women access them or how providers, chemists, women and their partners perceive medical abortion. The emergency contraceptive (EC) pills category were being advertised because they got the OTC nod from the concerned regulatory authorities. Then suddenly certain sections took an objection to the advertising asking that it be stopped. Rather than stopping the advertising of such products, chemist must be held responsible about educating the consumer in the right manner about such products. In this case, we have to tell the consumer clearly that EC pills are used in emergencies, and are not for regular use. So it's how you say it and what the advertisement says that you want to regulate, but not stopping the advertising.

Rakesh Pahwa and co-workers (2008) in their research article “Role of pharmacist in safe use of medicines” analyzes the role of chemists in the changing scene of OTC marketing. The pharmacist is now no longer merely a supplier of medicines and a concocter of medicinal products. In the present scenario, the pharmacist is a coordination centre between different members of healthcare team and the patients. Hence, proper role and involvement of a pharmacist in safe use of medicines and overall healthcare programme becomes very crucial as sale of OTC medicines is not as well regulated in India, the general perception is that these are risky and harmful. newer molecules like Lipitor is now being actively considered for such a status, the two most powerful advantages of OTC drugs are their cost and accessibility that could counter all arguments against them. In their fight for shelf space, the OTC drug manufactures are forced to keep prices at minimum, thus providing cost-effective remedy for such patients. India being a very large territory geographically, even more than half-a-million drug retailers have been unable to cover entire territory to make even commonly used medicines available to a large section of society, especially in the smaller towns and rural areas. Self medication seems to be the simplest thing to do when we are sick, especially when we aware of our illness. It was also revealed by the researchers that it is very risky as the danger of self medication can have serious implications, but once you get to know the name of the drug and its over-the-counter (OTC) brand names, then people do prefer chemists over consulting a doctor.

Neeraj Dixit (2010) “This paper also tries to find out the changes by the pharmaceutical companies regarding the 'product' and tries to find out if there is any significant preference towards the marketing strategy changes of the Indian Pharmaceutical companies post WTO product patent regime. Introduction of new molecules is the most preferred marketing strategy being pursued by Indian Pharmaceutical companies have to
frame strategies for marketing Pharmaceutical products and companies require more field force to remind their direct customer (doctor) of their products on a daily basis. Moreover field force should have good knowledge of product schemes/offers and good rapport with retailers. Field force also ensures availability of their products to convince doctors and PUSH their products. The researcher also revealed that companies need to bring some very serious strategic and operational level issues such as increased competition, low level of customer knowledge (doctors, retailers, wholesalers), good product mix and excellent marketing strategies but poor customer acquisition, very high attrition rate of the sales personnel, very high territory development costs, the number and the quality of medical representatives, busy physicians giving less time for sales calls, virtually no mechanism of sales forecasting from field sales level, leading to huge deviations, absence of analysis on the amount of time invested on profitable and not-so-profitable customers and lack of time-share planning towards developing customer base for future markets. The study finds that majority of 62 Pharmaceutical companies surveyed accepted that changes in marketing strategy have taken place.

2:5 ROLES OF DRUG MANUFACTURER, DOCTORS AND PHARMACIST IN SELF-CARE

The critical issues involved in self medication are providing truthful and knowledgeable information regarding drugs, which can be achieved through direct to consumer advertising and also promotion through the public media. Pharmacists and doctors play the most important role in creating awareness about self-medication. Responsible self-medication improves public health and can be used to prevent and treat symptoms and ailments that do not need medical consultation or oversight. This reduces pressure on medical services, especially when these are limited. For those populations living in rural or remote areas where access to medical services may be difficult, patients are able to control their own conditions to a greater extent.

Self-medication among the Indian population is most influenced by patient satisfaction with the healthcare provider, cost of the drugs, educational level, socioeconomic factors, age and gender. Specific pharmacovigilance is deemed to be essential. It is imperative for the patient, pharmacist and physician to report any adverse events, which will help the drug industry improve the formulation or withdraw a drug from the market, in case the effects are detrimental. Stress should be laid on periodic studies on the knowledge, attitude and practice of self medication that may give insight into the changing pattern of drug use in the Indian society.

Treatment choice among the urban population in India is more influenced by the workplace, workgroup and information they gather through scientific inquiry. The Indian drug industry, through various mediums, keeps the country updated about their activities. However, all this information does not serve any purpose for the illiterate rural masses that form 70% of the total population. They are most influenced by socio-cultural and economic factors. Neither do they have access to nor an inclination to gather information. They trust the doctors and more so the pharmacists. Therefore the role of a pharmacist is most vital especially in the Indian context. According to the 2006 Drug Policy, the government will be allocating budgetary resources to the National Pharmaceutical Pricing Authority (NPPA) to carry out consumer awareness campaigns involving consumer education and empowerment through print and electronic media. Programs and publicity will be carried out both in English and other Indian languages in order to reach out to the rural population. The Consumer Affairs Department is formulating a helpline in order to address consumer grievances regarding the quality, pricing, availability and accessibility.
of drugs. A dedicated website, providing all possible pharmaceutical drug related information, is also underway. However, it is to be noted that unless the country rises to improve its literacy rate, any amount of awareness programs and campaigns will be futile. ‘Responsible’ self medication is best achieved through literacy and education, which invigorate inquiry. Medicines play a crucial role in saving lives, restoring health and preventing diseases and epidemics. The role pharmacist has been emerging continuously over the past three decades so as to cater the modulating needs of society. The pharmacist is now no longer merely a supplier of medicines and a concocter of medicinal products. In the present scenario, the pharmacist is a coordination centre between different members of healthcare team and the patients. Hence, proper role and involvement of a pharmacist in safe use of medicines and overall healthcare programme becomes very crucial

**Role of Drug Manufacturers**
The International Pharmaceutical Federation and The World Self-Medication Industry, states the responsibilities of the manufacturers of nonprescription medicines are:-
1. The manufacturer has a responsibility to ensure that marketing methods encourage people to treat medicines with care and, to that end, not to take any action which could encourage people to buy excessive quantities of a medicine,
2. The manufacturer has a responsibility to ensure that claims made in the advertising of a medicine can be substantiated scientifically, meet national regulations, industry guidelines and internal company controls and do not encourage inappropriate use.
3. The manufacturer has a responsibility to provide medicines which are of a high standard of safety, quality and efficacy and meet all legal requirements for packaging and labeling and should work towards a world-wide standardized format for information on labels essential for pharmacists to enable them to provide appropriate advice to members of the public.

**Role of Pharmacists**
WHO defines the role of the pharmacist in self-care and self-medication as that of a communicator, quality drug supplier, trainer and supervisor, collaborator and health promoter. A pharmacist is the link between the people and the Pharmaceutical industry, informing the industry about ADR and other quality and price related issues. He is regarded as a navigator guiding the consumers to better health.
The International Pharmaceutical Federation and The World Self-Medication Industry lay down the responsibilities of a pharmacist as follows:-

a) Pharmacists have a professional obligation to report to the regulatory authorities, and to inform the manufacturer, of any adverse event encountered by an individual which may be associated with the use of a medicine purchased without a prescription
b) Pharmacists must have a professional obligation to provide sound, objective advice about self-medication and the medicinal products available for self-medication.
c) Pharmacists should encourage members of the public to treat medicines as special products to be stored and used with care and, to that end, not to take any action which could encourage people to buy excessive quantities of a medicine.
d) Pharmacists must recommend that medical advice should be sought where it is recognized that self-medication is not appropriate
Pharmacists in urban and rural India are highly trusted and considered to be knowledgeable. Proper training of the pharmacist helps in getting rid of such products, in the long run, the manufacturing companies also have an important role to play by being more socially conscious and implementing proper marketing techniques, and not just focusing on increasing the sale of such products to make more profits. Chemist and pharmacologists should be more responsible while dispensing drugs. If drugs have to expand into grocery stores or post offices for easy availability, pharmacologists should be able to educate grocers about the effects of the drugs they intend to sell.

Role of Doctors
Doctors in India are considered nothing less than gods by most rural people. Their blind faith symbolizes the reverence a doctor holds in the Indian society. Using this powerful position, doctors can reach out to people directly and via media, whenever necessary, to enlighten them about the rational usage of drugs.

Doctors can curb use of unethical and irrational drugs by educating patients. They play a vital role in influencing their patients’ pattern of selecting and administering drugs. Doctors believe that people are not equipped enough to medicate themselves, some encourage people to inculcate self-meditative habits which will make people more responsible to claim good health care facilities and non-spurious and authentic drugs.

They must inform and instruct people about responsible self-medication.

The fact that doctors in certain rural areas themselves are ill-informed is a serious problem there have been instances where doctors have knowingly not informed the patients about the existence of an over the counter drug, in order to procure fees. It is the attitude of the doctors that needs to be changed. Poverty at times lures them to propagate and promote drugs that are given to them by Pharmaceutical representatives, who give incentives for such promotion.

2.6 REVIEW OF THE STATUTORY WARNINGS, LAWS AND POLICIES
In India drugs are mainly divided into prescription and non-prescription drugs. Prescription drugs fall under Schedules H and X of the 1940 Act. Schedule H consist of prescription drugs like Antibiotics etc with the symbol Rx. Schedule X includes amusable and habit forming drugs requiring double prescription. Preparations containing Secobarbital, Methamphetamine Amobarbital, Amphetamine, Glutethimide, and Meprobamate X.

Nonprescription drugs fall under Schedule K of the Act. Currently those drugs, which are not covered under Schedule J, X, H, or G and their formulations (except their products for external applications) can be called OTC drugs. Since there is no schedule assigned for OTC drugs in particular, it can be safely deduced that drugs which are not prohibited by law to be sold without prescription are permitted to be sold over the counter.

Schedule K includes household remedies, contraceptives, ophthalmic ointments of the tetracycline group of drugs, certain oral salts, medicated dressings and bandages for first aid and certain homeopathic medicines. As per the Drugs and Cosmetics Act and Rules, there is no separate category of drugs called OTC drugs. Section 13 of Schedule K specifies household remedies that can be sold over the counter on fulfillment of the following conditions:-

(a) These drugs are sold only in a village having population of not more than one thousand persons and where there is no licensed dealer under the Drugs and Cosmetics Act;

(b) The drugs are sold in the original unopened containers of the licensed manufacturers
(c) When the drugs are sold under clause (a) condition 3 under “Conditions of license” of Form 20-B shall not apply. Condition 3 of Form 20-B states that (i) no drug shall be sold unless such drug is purchased under a cash or credit memo from a duly licensed dealer or a duly licensed manufacturer; (ii) No sale of any drug shall be made to a person not holding the requisite license to sell, stock or exhibit for sale or distribute the drug., except for those, which have been specifically exempted by inclusion in Schedule K of D&C Rules.

(d) The drugs do not contain any substance specified in 1, (Schedules G, H or X)

Indian Laws regulating Indian pharmaceutical industry.

There are several other laws which have a bearing on pharmaceutical manufacture, distribution and sale in India. The important laws for OTC products are:

The Pharmacy Act of 1948 regulates the profession and practice of pharmacy. The main object of this Act is to prohibit the dispensing of medicine on the prescription of a Medical Practitioner otherwise than by, or under the direct and personal supervision of, a ‘registered pharmacist’. S.36 (iii) (e) of the Act states that where a registered pharmacist has not used due diligence in enforcing compliance with the provisions of the Drugs and Cosmetics Act in his place of business and by persons employed by his or by persons under his control is an offence. In spite of clear legal provisions prohibiting the sale of prescription drugs without a prescription, the practice is widespread.

The Drugs and Magic Remedies (Objectionable Advertisement) Act of 1954 aims at controlling objectionable advertisements published in newspapers or magazines or otherwise relating to alleged cures for venereal diseases, sexual stimulants and alleged cures for diseases and conditions peculiar to women. These advertisements tend to cause the ignorant to resort to self-medication with harmful drugs and appliances, or to resort to quacks who indulge in such advertisements for treatments which cause great harm. The pharmaceutical companies advertise certain drug preparations with excessive and misleading claims in violation of Drugs & Magic Remedies Act.

**GOVERNMENT POLICIES:** The government argues that the profile of Indian consumers differs from those of Americans. According to a health ministry official, the idea is to provide greater access to 'household remedies', which have been in use for a long time and can therefore be consumed safely. Besides, these medicines have less risks of abuse, the official said.” The government is skeptical about regulatory issues involved in monitoring the grocery shops, when it is already difficult to monitor the existing pharmaceutical retail and distribution chains. The government through the Health Ministry and the Department of Chemicals and Petrochemicals is considering introducing, as nonprescription drugs, widely used drugs such as painkillers and cough syrups at grocery stores in order to facilitate easy accessibility.

In anticipation of widening the sales of OTC drugs beyond a chemist, the Health Ministry is set to make changes to Schedule K of the Drug and Cosmetics Act, and relieving these drugs from price control. On comparative analysis on the US OTC market, the government expressed concern over the low awareness and education level of the Indian consumer. It cannot be denied that many people in India cannot even read the information on the brochure. Currently there are 15 drugs under Section 13, relating to sale of household remedies, of Schedule K of the Act and the OPPI in July 2005 sent a recommendation to the Drug Controller General of India to add 12 other drugs to the list. The OPPI in 2002 had recommended 57 drugs to be brought under the OTC drug category, but the recommendation was rejected.
Labeling of O.T.C. drugs should be more detailed, giving all indications, contraindications, common side-effects and danger-signals. The labeling should be made in English, Hindi and a regional language. It should accompany every pack of 10 tablets. Information about scientific treatment at home, of minor ailments, with the help of O.T.C. drugs should be widely and repeatedly publicized by the state media. Advertisements of O.T.C. drugs should be reviewed by an expert committee before release. This committee should have a consumer's representative on it to put forward consumers' viewpoint about the impact of these advertisements.  

The need for promoting appropriate use of drugs in the health care system is not only because of the financial reasons with which policy makers and manager are usually most concerned, but also for health and medical care of patients and the community. With 35% of the world's spurious drugs produced in India, according to a WHO survey, it alarms the government to make existing laws regarding OTC drugs strong enough to ensure their rational sale and use. Overwhelmed by poverty, illiteracy, superstition and faith in magic remedies, the country needs a strategic plan to educate and create awareness not only amongst its rural populace but also amongst many urbanites that dwell on their own theory of medication.

Switch of Rx drugs to OTC is of great significance in the US and other developed and regulated markets, but India is not ready for that change. In spite of all the challenges that OTC drugs seem to be posing, most others believe that the rewards are worth taking the risk. However these challenges can be tackled by India only in the long run.

Usage of Drugs “Pharmaceutical promotion is a persuasive communication and the promotional materials are major source of drugs information to the health-professional. So this message should be factual, evidence based, unambiguous and balanced. Unfortunately in many countries, especially in developing countries, the promotion is not evidence based and also inaccurate. Inappropriate promotion leads health professionals and also the public to use of irrational use of drugs. For example, Limited budgetary allocation for health care has been one of the main causes of unsuitable, non-productive and irrational use of drugs in India. The 2006 Drug Policy emphasizes on rational use of drugs and has allocated budgetary resources to resolve the irrationality of drug usage in India. However, the key lies in continued education through discussion. Apart from promoting appropriate use of pharmaceuticals in health care delivery, India should also aim at providing health related quality of life for its community.

2.7 CONCLUDING REMARK

As sale of OTC medicines is not as well regulated in India, the general perception is that these are risky and harmful. Even relatively newer molecules have been granted OTC status by FDA in common interest and a new molecules is now being actively considered for such a status, the two most powerful advantages of OTC drugs are their cost and accessibility that could counter all arguments against them. In their fight for shelf space, the OTC drug manufactures are forced to keep prices at minimum, thus providing cost-effective remedy for such patients. India being a very large territory geographically, even more than half-a-million drug retailers have been unable to cover entire territory to make even commonly used medicines available to a large section of society, especially in the smaller towns and rural areas. The common OTC drugs like painkillers, cough and cold preparation, balms etc, that can be sold in grocery stores and other shops without a drug
license, have been instrumental in taking care of basic immediate healthcare needs of patients. Any tightening of norms could severely impact availability of such medicines. Pharmacists, doctors and manufacturers together can help alleviate the challenges associated with introducing over the counter drugs. They can inform shop-owners, grocers and super market managers but also the public at large. Self medication seems to be the simplest thing to do when we are sick, especially when we are aware of our illness. But how safe is it to self-prescribe? Practically speaking it is very risky as the danger of self medication can have serious implications, but once you get to know the name of the drug and its over-the counter (OTC) brand names, then people do prefer it over consulting a doctor and taking a prescription (Rx) drug. Pharmaceutical companies have to consider a few parameters when deciding if a particular product can be converted from Rx to OTC. The drug in question has to have a significant amount of experience in the market, its safety and stability profile should have been established over the years, and most importantly, the drug is for minor health problems.

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48 Responsible Self-Medication, supra.

49 E-mail from Dr.santosh kamble to Rajesh kanthe (on file with the author), 2 June 2007

50 Traditional medicines such as Ayurveda (which is explained later), Siddha and Unani are covered under Chapter IV-A of the *Drugs and Cosmetics Act of 1940*, Chapter XVI of the 1945 Rules and Schedule E & T.
According to Section 2 (i) of the Pharmacy Act a "registered pharmacist" means a person whose name is for the time being entered in the register of the State in which he is for the time being residing or carrying on his profession or business of pharmacy. And under Section 2 (h) "register" means a register of pharmacists prepared and maintained under Chapter IV of the Act.


