CHAPTER II
REVIEW OF LITERATURE

A literature overview based on theoretical concepts and on research findings had been provided in order to glean a better understanding of prevalence of the practice of purchase of OTC medicines in medical shops without prescriptions, role of pharmacists in OTC purchase decision and consumer protection.

2.1. RELATED LITERATURE

Literature search encompasses pertinent facts, figures, findings and discussions arranged in the following sub headings:

2.1.1 Self medication
2.1.2 OTC usage prevalence
2.1.3 Reasons for the purchase of OTC medicines
2.1.4 Ailments for which OTC medicine is purchased
2.1.5. Relationship between the purchase of OTC medicines and the socio-demographic factors of the respondents.
2.1.6. Role of pharmacists in the purchase of OTC drugs by consumers.
2.1.7. Reported side effects of OTC medicines
2.1.8. Level of awareness about possible ill effects of OTC medicines.
2.1.9. Legal protection through Consumer Forum/Council/Act

2.2. Ancillary findings

i) Source of information about OTC medicines.

ii) Availability of fake medicines in pharmacies
2.1.1. Self medication

Self-medication Definitions/concepts

There are some differences in the definitions of self-medication; for example, WHO consultative group of experts defined self-medication as the selection and use of medicines by individuals to treat self-recognized illnesses or symptoms [WHO Report, 1993]. Self-medication is also defined as obtaining and consuming one or more of drug(s) without the advice of a physician either for diagnosis, prescription or surveillance of the treatment.¹

A self-medication drug is a drug (the grantees for which are provided by marketing authorization approval and dispensation and advice by a pharmacist) specifically suitable for use without any physician’s prescription²

2.1.2 OTC usage prevalence

The prevalence of Over the counter medicine is found to be common in many countries. High levels of self-medication practices with over-the-counter (OTC) medicines and complementary and alternative medications (CAM) have been reported in many countries;³ Eisenberg, 1998⁴; MacLennan, 2006⁵; Hanlon, 2001⁶; Easton, 2007⁷). According to the surveys

conducted by the World Self medication Industry, during the year 2007, the percentages are the highest in the United States and in South Africa.

It is estimated that within any two day period, over one-third of the U.S population uses an OTC product (Rabin and Bush, 1975; Helm, 1977). Research suggest that the use of OTC medicines is common from young age (Dengler and Roberts, 1996; Chambers, Reid, McGrath and Finley, 1997; Ellen, Bone and Stuart, 1998; Lam and Shek, 2006). Survey and diary studies of medicine taking behaviour indicated that 70% to 80% of illness is managed by self-care without the intervention of the physician [Gore, P.R. and Mahavan S,1994].

Self-care is a predominant therapeutic activity consisting 30-40% of the disadvantaged populations including women, elderly, ethnic minorities and poor in Bangladesh. Self-medication in a population with low literacy level like Bangladesh are very challenging, which poses risks such as incorrect diagnosis, absence of knowledge of alternative treatments, irrational use of drugs and neglecting side effects and drug interactions. Study showed that around 30%--

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40% of disadvantaged population including the women, elderly, ethnic minorities, poor / ultra-poor undertake self-medication for managing illness (Ahmed, 2005)\(^\text{15}\).

There is a broad range of oral and topical OTC preparations used frequently by the general public to treat common health problems ranging from headache to tinea pedis (Athlete’s foot). In fact, OTC medications such as analgesics, decongestants, and antihistamines are among the most frequently used of all medications in the United States. Currently, 35% of adult Americans use OTC medications on a regular basis. OTC medication use in children is twice that of prescription medication. Retail sales of OTC medications are over $17 billion. Cough/cold and allergy remedies, analgesics, and antacids/anti-gas products are the most common preparations for oral ingestion purchased. Toothpastes, oral antiseptics/rinses, and first aid treatments are the most common topical preparations purchased\(^\text{16}\).

Studies on adults indicated that most people are able to discriminate between minor and major ailments and individuals themselves without visiting a physician deal with 87% of minor problems. Another study found out that more than 60% of the reported illnesses were dealt with using OTC drugs, with no doctor being contacted [Betsy S., et al. 2001\(^\text{17}\)]. Still in another survey it was reported that in many parts of the world up to 80% of illness episodes are self-medicated with modern drugs and even when formal health care channels are used, it is often the consumer not the prescriber who determines whether and how the drugs are used [WHO, 1998\(^\text{18}\)].


\(^\text{16}\) www.acpm.org.


Consumption of antipyretic/analgesics on the advice of non-qualified people were as common as medical prescription [Antonov, K. and Isacson, D.,1996; Montano, et al, 1997]. In retrospective research on self-medication, people often cannot recall even the name of the drug, much less the dosage schedule or course of treatment [Laurie, J. P., 1989]

The use of OTC medicines seems to prevail in many countries across the globe. In a Canadian survey (2005) 44% of consumers said that they had practiced more self-care over the past year than the year before, and 52% expected to be practicing more self-care in future years. In Hong Kong, the use of over-the-counter (OTC) medications is popular in the local population. It was found that 65% of the respondents used OTC medications [Lam, 1994] and that 32.9% of outpatients had taken OTC two weeks prior to their visits [Granek-Catarivas, 1994].

In most less developed countries almost any drug available on the market may be purchased over the counter (Ferguson, 1981). More than 3 million young people in the United States, aged 12-25 years, are thought to have used OTC cough and cold medications non

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medically in 2006. (SAMHSA, 200525). Whether one lives in a developing country or in a
developed one, the sources of information are similar. A person may seek advice from ‘an older
person in your household who possesses the knowledge of simple herbal remedies for common
illnesses’ (Nepal, 2002)26 or with a pharmacist because they can ‘provide a good help to assess
the symptoms’ and ‘spend time explaining how to use the medication properly’ (Singapore
2005)27.

A study from the US showed that up to 96% of patients of all ages surveyed used OTCs
and aspirin was the most commonly used drug.( Darnell, 1986). A further survey of community
patients aged 75 years and over in the UK found almost half the patients admitted to taking non-
prescribed medicines. (Blenkiron, 1996)28 and a further study found just over a third of the OTCs
used by elderly people in the community were analgesics or aspirin (Cartwright, 1988)29.

A study conducted in 2006 showed that about half of the antibiotics were sold without
any prescriptions, and even ordinary people without any knowledge of medicine asked the drug
seller for specific antibiotics (Mamun, Tabassum, 2006)30. The prevalence of over the counter
medicines is found to be of an alarming rate in India. As of October 2011, India’s pharmaceutical

25 Substance Abuse and Mental Health Services Administration (SAMHSA). National survey of drug use and health.


27 Singapore (2005). Advice giving on self-medication: perspectives of community pharmacists and consumers in

28 Blenkiron, P. The elderly and their medication: understanding and compliance in a family practice. Postgrad Med


30 Mamun KZ, Tabassum S, Shears P, Hart CA. A survey of antimicrobial prescribing and dispensing practices in
market totaled at Rs. 50,000 Crore. Currently, India ranks 11th in the global OTC market size as sales continue to increase (growing at an annual rate of nearly 11%)\textsuperscript{31}

In many developing countries, over 80% [Homedes N., and Vgailde A, 2001\textsuperscript{32}; Kumud, K., Kafle, et al. 1992]\textsuperscript{33} of all drugs are purchased by people for themselves or a family member without a prescription. Self-medication is documented as an integral part of health care therapy in developing countries such as Ethiopia, Cameroon, Uganda and Mexico [Report on Drug Utilisation, 1997]\textsuperscript{34}.

There is no ‘prescription only drug’ in Bangladesh at present. One can get any drugs from anywhere. Only need is money; no prescription indeed (Islam, Goldman, Kunin, 1996)\textsuperscript{35}. Over the counter (OTC) drugs have emerged recently as drugs of serious misuse across Bangladesh, and other neighboring countries.

One report estimates that there are four million drug misusers in the South Asian region, with Bangladesh accounting for nearly 500,000 (Mudur, 1999)\textsuperscript{36}. Self-care is a predominant therapeutic activity consisting 30-40% of the disadvantaged populations including women, elderly, ethnic minorities and poor in Bangladesh. Self-medication in a population with low

\textsuperscript{31} http://www.indiaoppi.com/IndiaOTCpharmaProfile2011.pdf


\textsuperscript{35} Islam N. Goldman JD, Kunin CM Ask the expert, APUA (Alliance for the prudent use of Antibiotics) Newsletter 1996, 14 (2). (URL: http:www.tufts.edu/apua/Newsletter/Islam.html)

\textsuperscript{36} Mudur G. Abuse of OTC drugs risinfg in south Asia. BMJ 1999; 318: 556
literacy level like Bangladesh are very challenging, which poses risks such as incorrect diagnosis, absence of knowledge of alternative treatments, irrational use of drugs and neglecting side effects and drug interactions. Study showed that around 30%-- 40% of disadvantaged population including the women, elderly, ethnic minorities, poor / ultra-poor undertake self-medication for managing illness (Ahmed, 2005)\footnote{Ahmed S.M. Exploring Health seeking behavior of disadvantaged populations in rural Bangladesh (Ph.D dissertation, No. 05/433) Karolinska University Press 2005, Sweden (Accessed on September 10,2011) Source: http://diss.kib.ki.se/2005/91-7140-435- Madur G. Abuse of OTC drugs rising in South Asia, BMJ 1999,318:556.}

Community based studies in Africa, Asia and Latin America have found that up to 70% of illness episodes are self-treated with modern/allopathic pharmaceuticals [Kroger Geest S., 1983\footref{Kroger} ; Abosede, O.A., 1984\footref{Abosede}].

2.1.3. REASON FOR OTC USE

People once get used to consuming medicines for mild illness develops low tolerance to ailments of all kinds. Lowered thresholds of tolerance not only result in greater overall use of existing medications, but also proliferation of new pharmaceutical products which both respond to consumer demands and generate new dissatisfactions. The cycle continues: an increased availability of products spurs additional changes in thresholds of discomfort, resulting in altered definition of what is “normal” or “natural” and driving the need for new, improved products.

An individual decision to use available drugs to alleviate discomfort, prevent illness, and enhance health is influenced by myriad factors. These factors range from cultural sensitivities and preferences for specific forms of medication to economic considerations, which influence medicine choice in the market place; from political issues, which regulate medicine availability

to marketing campaigns, which creates as well as respond to consumer demands [Nancy V. and Markm N., 1997] ⁴⁰.

When people are unwell they cannot be sure whether their condition warrants a prescription or a non-prescription medicine, but a considerable number of factors may influence their decision to go to the health care provider. According to the Association of European Self-medication Industry (AESGP) these are:

- The perceived seriousness of the symptoms and the extent to which they may have occurred before;
- The cost, if any, of consulting a health care provider;
- The time needed to go to the health care provider;
- Any other costs connected with going to the health care provider such as loss of earnings; And
- The known or estimated cost of purchasing the prescribed medicine and how that amount compares with the estimated price of a non-prescribed medicine [AESGP, 1998] ⁴¹.

Taking non-prescription medicines is the initial response in almost half of all illness episodes, particularly for symptoms viewed as non-serious [Lau, 2000] ⁴². The reasons for self-medication mentioned in the literature are mild illness, previous experience of treating similar illness, economic considerations and a lack of availability of healthcare personnel. The most

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⁴¹ Association of the European Self-medication Industry (AESGP). Influences on the Consumer to see a Doctor, May 1998. www.AESGP.com

common medications used for self medication are analgesics and antimicrobials [Hughes, 2001; Shankar, 2002]. Study on self medication shows that it is influenced by many factors such as education, family, society, law availability of drugs and exposure to advertisements [Montastruc, 1997; Habeed, 1993]. A high level of education and professional status has been mentioned as predictive factor for self medication [Martins, 2002].

The resurgence of interest in self-care in health and self-medication is associated with several factors. These include:

- Self-medication provides a more affordable though often less desirable response to illness when the financial cost of health care providers fees are unaffordable and in convenient in obtaining professional care are considered;
- Some people are prompted to self-medicate due to lack of faith in the health service for treatment of “disorders” as distinct from “disease”;
- There appears to be an increased emphasis on taking personal responsibility for own health, and the sheer availability of a greater number of products with which to experiment;

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• Symptomatic relief with OTC medications allows individuals to manage chronic complaints, especially those not validated by doctors. They feel more capable than doctors on assessing the fluctuations and flare-ups of their ailments and

• When both complaint and its prescribed treatment are routine or familiar, individuals may take charge of an illness episode unless the complaint continues beyond the expected duration or symptoms unfamiliar are seen [Hughes, C.M.et al, 2001].

While in a developed country like the US many patients consider self-treatment with over-the-counter medicines as a cost and time-saving alternative to doctor visits for common ailments, a country like South Africa perhaps relies on self-medication more as a major contributor to health maintenance because of lower levels of infrastructure and professional staff. In the consumer survey conducted in many nations it was found that the percentage of OTC use was 37% in South Africa, 33% in the U.S., 28% shared by Australia and Germany, Spain, U.K and Sweden with a percentage of 24, Switzerland 22%, Mexico 21% and Italy 20%.

A literature review of variables reported to influence the use of complementary medicines by consumers suggested that the emergence of postmodern values provided the best explanation of consumers' interest in OTC medicines. Postmodern values involved "a new set of beliefs about nature, science, holistic medicine, rejection of authority, individual responsibility and consumerism" [Easton, 2007]. Higher prescription charges encourage self medication among those who pay charges. (Colwell J, 1993)

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Pharmaceutical companies are refocusing their over the counter (OTC) strategies, as there is increased self-medication and consumer interest in wellness focused OTC products. In fact, the OTC segment is projected to have a higher growth rate than prescription medication. But OTC products require a different set of skills where doctors also play an important role. Peak performance at work and job security are now more important to consumers meaning that preventive remedies, convenience OTCs, energy boosters, brain boosting supplements and formulations for sight and hearing provide growth opportunities, along with contraceptives for women who want to work longer before having children. Dineshkumar. B and etal (1995)\(^\text{52}\)

A small amount of subjects revealed a considerable degree of satisfaction towards being able to talk to pharmacists about matters which they could not ask doctors, (Hayashi, 2005)\(^\text{53}\) but the study did not elaborate on the nature of such matters and the reasons behind this. Time constrain for doctors in each consultation, fear of embarrassment about asking inappropriate questions, feeling pharmacists were more approachable could all fit in the context.

Easy accessibility of pharmacists to answer any health-related problems, accessed by convenient opening hours of pharmacy 20 to their availability, (Mayhew, 2001)\(^\text{54}\) can be concluded as the main reason why members of the public seek help from pharmacists. The perceived value of pharmacists in providing such advice is mixed and highly dependent on the primary healthcare provision environment in each individual country.


A study was done in Northern Ireland describing the frequency of visits and the reason for paying a visit to the pharmacy for treatment of minor illnesses lay hugely on the seriousness of the problem and practicality to get a doctor’s appointment. A particular regular pharmacy was chosen because of its proximity to the respondents’ home. They reported a majority of interviewees (67%; n= 903 and 61.1%; n=1000 respectively) would go to the pharmacy because they felt the symptoms were not serious enough to see a doctor. The second likely reason was that they did not have time to wait for a doctor’s appointment (14.3%, 11.3%). These articles also added the second most likely reason for visiting the same pharmacy to be the good advice offered, with percentages of 13.7 and 18.3 (McElnay, 1993)\textsuperscript{55}.

Wazaify adopted a similar method he used in Northern Ireland to find out the reason why Jordanians visited a particular pharmacy. The primary reasons were still proximity to home and the good advice offered (26.2%, 20.9%; n= 1085) (Wazaify, 2008)\textsuperscript{56}. In some African countries which are not as well developed, pharmacies are often the first port of call for treatment. This is highly correlated to the uneven distribution of health clinics in rural parts of the country, where pharmacies have become their only available choice. Also people from low income communities often cannot afford the double cost of going to see doctors and buying medicines from pharmacies; they would rather go directly to the pharmacies to get the medicines. (Viberg, 2007)\textsuperscript{57}. Helen Boardman (2005)\textsuperscript{58} Medicines to treat cold and flu symptoms were the most frequently reported OTC purchase type.

2.1.4. Ailments for which OTC medicine is purchased

Studies done on self-reported prevalence study of illnesses that prompted self-medication showed that cough/cold/influenza, digestive disorders, accidental injuries, headache/dizziness, anxiety/insomnia, skin problems, asthma, liver disease, fever, boils were the prevalent health problems [Deshpande, S.G., and Tiwari, R., 1997]^{59}. Medicines to treat cold and flu symptoms were the most frequently reported OTC purchase type. Symptoms such as cold/flu, cough, sore throat, headache, heartburn, constipation, and indigestion are reported by respondents as disorders that they tend to self-treat. (Wilkinson, 1987^{60}; Seagall, 1990^{61}; Gross 1990^{62}; Bell 2000^{63}). Colds are a very common type of minor illness in which most people can self-treat by using OTC medications, this expenditure might be unnecessary. Temin provides a piece of evidence to this point (Temin, 1982)^{64}

2.1.5. Relationship between socio demographic variables and usage of OTC medicines

Self-medication is affected by socio demographic and socio-economic factors [Somsen, G.A., and Schut, N.H., 1998]^{65}. Quantitative studies indicate that there is correlation between increased self-medication activity and demographic factors such as morbidity, income, education

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^{58} Helen Boardman, Martyn Lewis and Peter Croft, J Public Health (September 2005) 27 (3):254-262.
^{61} Segall A. A community survey of self-medication activities. Med Care 1990; 28: 301-10
(schooling), gender, age and absence of periodic consultation. These have been found to be significant statistical factors in self-medication [Caulin, C., and Cranz, 2000]66.

Marital status, educational level, socio-economic status and social network conditions were found to be of minor importance in OTC purchase [Antonov, K., and Isacson, 1996]67. Greater educational attainment and poorer self-rated health have been associated with higher use of OTC in some studies (Amoako 200368, stroller, 198869).

2.1.5. a) Age as the determining criterion for usage of OTC medicine

The relationship of age and OTC use is equivocal in the literature (Hanlon and Fillenbaum et al, 2001)70. Self-medication increased with age [Huang, L.H., 1996]71.

Young people may use cough or cold remedies to alleviate coughing or wheezing associated with asthma. What do young people know, for example, about the dosages and side effects of drugs they take, or which drugs can cause drowsiness? Do they know that aspirin causes stomach bleeding? These are highly pertinent questions, as the reading ability of some pupils, especially younger pupils and those with learning difficulties, is likely to be less than that

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70 Stoller EP: Prescribed and over-the-counter medicine use by the ambulatory elderly. Med Care 1988 , 26(12):1149-1157
needed to understand literature accompanying some OTC drugs. (Nicoll A., 1985)\textsuperscript{72}. Teenagers, especially 14- to 15-year-olds, act more independently than younger children in making decisions about what to take and when to use nonprescribed medications (Dengler, 1996)\textsuperscript{73}.

A cross-sectional population survey of a random sample of children aged under 12 years (n = 6000) was carried out by Hämeen-Anttila in Finland in spring 2007, with a response rate of 67%. A questionnaire was sent to their parents. The predictors for the use of OTC medicines by the child were young age and the use of OTC medicines by a parent.

\textbf{2.1.5. b) Gender as the determining criterion for usage of OTC medicine}

The most striking difference between the groups is in the reported use of OTC painkillers, as two-fifths of older girls had used them compared with one-fifth of other groups. In most instances, there are no differences between boys and girls aged 11-12 years (Regina Dengler and Heather Roberts, 1996). To obtain prescription stimulants, a physician must be visited, and men generally are less likely to visit a physician than women (Aday, 1980)\textsuperscript{74}.

Some studies have indicated that women are more likely to self-medicate than men [Nancy V. and Markm N., 1997]\textsuperscript{75}. A survey done in Australia on patterns of medication use during pregnancy showed that the women used an average of 0.7 to 0.8 prescribed and 2.3 to 2.6 non-prescribed drugs (a total of 3.1 to 3.3) during the three pregnancy trimesters, compared with

1.0 prescribed and 2.2 non prescribed drugs prior to pregnancy. Use of a prescribed and non-prescribed drug use was 96 to 97% across trimesters [Henery, A., and Crother, C., 2000].

In a prospective study on drug use in France during pregnancy in outpatient department of a hospital showed that 84% of the pregnant women reported drug consumption, with an average of two drugs per week. And in a study done in Brazil, the prevalence of use of at least one medicine was 97.6% with an average of 4.2 drugs per woman. The prevalence of use of drugs by prescription and self-medication were 94.9% and 33.5%, respectively [Bouvier, N., et al, 2000; Damase-Michael, C, 2000].

2.1.5. c) Education as the determining criterion for usage of OTC medicine

In India (1995), it was shown that literate people were 76% more likely to self-medicate than illiterate people. Other studies (Singapore 2005; Brazil 1997; China 2003; Nepal 2002) confirmed that self-medication increases with education level. In Portugal (2004), a country that has experienced profound economic and social changes in the last 30 years and where the education level has increased tremendously, 74% of consumers believe that they should have access to many more non-prescription medicines. Studies show that college students used the frequently advertised products [Burak, L.J., and Damico, 1999 & 2000].

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2.1.5. d) Education income and gender as the determining criterion for usage of OTC medicine

The most extensive survey of the South Australian population in 2004 found that CAMs were used by 52.2% of the respondents with the greatest use in better-educated, higher income, women in the 25-44 years of age group living in a metropolitan area (MacLennan et al. 2006). None of the demographic variables tested, age, gender, education, tertiary education, income level and self-rated health was found to be associated with OTC use. (Lynn et al. 2009). Among the lowest income group there was up to 47% of self-medication and of which 46% of the drugs self-medicated were antibiotics [Gore, P.R. and Mahavan S., 1994].

Large-scale studies of OTC drug use have also been conducted. Data on whether the drugs had ever been used or used in the past year were collected for the National Commission on Marihuana and Drug Abuse (NCMDA Report, 1973). Its results provide a base from which to examine demographic differences among users and nonusers of sedative, tranquilizer, and stimulant proprietary drugs for a national sample of adults. The OTC drugs studies by the NCMDA are the same as those examined in this research. The commission concluded that only age and region were strongly correlated with OTC drug use. Other demographic variables such

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as education, sex, race, and community size were only marginally related to proprietary drug use during the 12 months prior to the interview.

Giachello (1982)\textsuperscript{83} analyzed OTC use for a national sample. The data were from a 1976 national study of access to medical care conducted by the Center for Health Administration Studies. Using a multiple regression approach, they examined the impact of a number of variables affecting use of OTC drugs during a reported episode of illness. They concluded that use of OTC is a function of the predisposing, enabling, and need characteristics of the respondents. The predisposing factors—the individuals' propensity to self-medicate—are basically demographic characteristics and are similar to those reported by the NCMDA (6). Enabling factors—the ability to obtain desired services—include income, education, and insurance coverage.

The relationship of age and OTC use is equivocal in the literature (Sharpe, 1985)\textsuperscript{84}. Greater OTC use was observed in females in the US studies that included multivitamin use Conn (1991)\textsuperscript{85} examined the relationship between older adults' use of OTC medications and mood, social, health and demographic variables. Interviews were conducted with 186 adults aged 65 to 99 years. He found that among other factors that predicted OTC medication use was age and income.


\textsuperscript{85} Conn VS. Older adults: factors that predict the use of over the counter medication. Journal of Advanced Nursing. 1991 Oct; 16(10):1190-6
During 1993, a study was conducted by Nielsen et al (2003) in Denmark with an objective to analyze the association among different types of medicine use and different measures of socio-economic position (SEP) in one and the same general population with a representative sample of the adult Danish population (n=16,690). Results showed that disability pensioners and self-employed individuals used less OTC medicine than salaried employees. Individuals with low income used more prescription medicines but not more OTC medicines, than those with high income. OTC medicine use was not associated with education for either gender.

Helen Boardman (2007) a cross-sectional survey of a stratified random sample of 10,000 adults aged 35 years plus. In the previous month, 59 per cent of respondents had collected a prescription medicine and 40 per cent had purchased an over-the-counter (OTC) medicine from a pharmacy, whereas only 12 per cent had asked for advice. Women were more likely to have obtained medicine or asked for advice (76 per cent), but nearly two-thirds of men had done so (63 per cent). Poor self-rated health was the key factor in obtaining medicine, both on prescription and OTC. Purchasers of OTC medicine were more likely to be younger and from higher socio-economic classes, whereas those who collected prescription medicine were more likely to be older.

Constanze Häußinger (2009) conducted an analysis to examine the health beliefs of pharmacy customers in Germany, the impact of those beliefs on over-the-counter (OTC)

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medication use, and associations with socio demographic variables choosing a random sample of 58 pharmacies in Saxony, Germany (10 questionnaires per pharmacy), invited their customers to take part in this study. One hundred twenty-three questionnaires (response rate 53.48%) were completed and returned. The outcome suggested that there were no significant associations between socio demographic variables and chosen drugs.

On the average 1.7 drugs are taken by women as compared 1.0 by men. Curative drug use rises sharply with age and preventive drug use also rises until age 75+, after which it drops. There is no overall relationship between drug use and education, and drug use and ethnicity. Drug use depends mainly on morbidity and age followed by attitudes about life and health, then on stress and least on social roles and one’s ability to take other health actions besides drugs. Overall, morbidity is the strongest predictor of drug use. It differs sharply by sex. Evidence suggests that women have more symptoms from acute and chronic conditions than men do, although their conditions are probably less life threatening than men’s. Women’s more frequent symptoms lead to more drug use [WHO,1993]. Factors that have contributed to increased demand for medication include: perceptions of illness and medicine; the impact of advertising and the media; and increasing reliance on commercial products or self-care. Medicine obviates the need to devote time and energy to healing activities or to the ‘down time’ necessitated by ill health. In this way medicines join the ranks of other timesaving convenient products to meet the demands of hectic lives [Nancy V. and Markm N,1997].

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2.1.6. Role played by pharmacists in OTC purchase

Today, more and more patients are asking for information to resolve their non-prescription medicine purchase and usage dilemma. And, the pharmacist is reportedly the most widely accessible, friendly and consulted source by consumers for non-prescription medicine information. Therefore, pharmacists are in a position to assess the patient’s problem and recommend an appropriate course of action. Pharmacists can deter healthy people from using costly or unnecessary health services or products and at the same time refer more ill people to appropriate health care providers and health services. In fact, the community-based pharmacies are in a unique position to provide medication services for their patients particularly in providing counselling on the use of prescription and OTC medications, monitoring of adverse drug reactions and provision of drug information to their community. Evidence of benefits and acceptance of the above expanded role of community pharmacy services have been shown by studies [Sarrif, A. 1994]91.

Pharmacy is seen as a place where prescription medicines are dispensed, with over-the-counter (OTC) medicines and household toiletries can also be purchased, and ‘pharmacist’ is the person who dispenses them. In the UK, it has been suggested that general public often recall pharmacist as ‘chemist’ in qualitative studies (Vallis, 1997)92.

Pharmacies (chemist shops and drug stores) are not only sites where medicines are bought and sold; they are also places where information and advice on common health problems and treatment is sought routinely. Such interactions have been reported to be convenient, time


A Canadian report indicates that pharmacists give advice on minor illness an average of 2.8 times per day. (Loh E, Waruszynski B, Poston J., 1996). Of all OTC sales that occur in a day, results have seen high rates for those occurring with advice in England (31 percent) and in Australia (47.8 percent). (Phelan MJ and Jepson MH. 1980; Blythe T and Armstrong B, 1977)

Patients take information and process it with their own cognitive framework, which is based upon their interpretation of their own experiences. The meaning that the patient attaches to the information may be quite different from the meaning that the pharmacist attaches to the information. (Donna Dolinsky, 1989)

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96 Ryan S. Canadian pharmacies service study: The willingness of consumers to pay a fee for private consultation with their pharmacist on both prescriptions and OTC products. Don Mills, ON: Upjohn Company; 1984.
According to an Irish report, around 22.3 percent of OTC sales are supported with verbal counselling. (Fisher CM, Corrigan OI, Henman MC., 1991)\textsuperscript{102} A Netherlands study determined 15 percent of OTC sales occurred with advice (Blom A and Rens J., 1989)\textsuperscript{103} Only 10 percent of products sold have been accompanied by a pharmacist’s advice in Sweden. (Marklund, Karlsson, Bengtsson, 1990)\textsuperscript{104}

An important aspect of the counselling process involving OTCs is who initiates the process. Krska and Kennedy asked consumers about their expectations and experiences when purchasing OTC medicines in the north of Scotland. They found that 70 percent of respondents wanted advice about symptoms or OTC products. As well, six in ten clients (59 percent) reported that they expected to be asked questions about their symptoms by pharmacists. Almost half of the customers (46.5 percent) expected to receive advice about the OTC medicines they bought. (Krska J and Kennedy, 1996)\textsuperscript{105}

An American study provides indirect information about how consumers think of pharmacists in this role. Gore and Madhavan surveyed 3,000 Americans on the credibility of four information sources (physicians, pharmacists, family members, and friends/colleagues) for OTC medicines (Gore P and Madhavan, 1993)\textsuperscript{106}. Only 458 subjects replied to the questionnaire; response was therefore low at 15.2 percent. The results found that acceptance of both pharmacist

\textsuperscript{104} Marklund B, Karlsson G, Bengtsson C. The advisory service of pharmacies as an activity of its own and as part of collaboration with primary health care services. J Soc Admin Pharm 1990; 7: 111-6.
and physician recommendation was high (75 percent and 76 percent, respectively). Comparatively, slightly over half of respondents usually or sometimes accepted recommendations from their family members or friends/colleagues. Participants were also asked to rate these four sources on three dimensions of credibility – expertise, trustworthiness, and empathy. Pharmacists were rated lower than physicians on all three dimensions. However, consumers believed that pharmacists were more expert and trustworthy than were family members or friends/colleagues. On the dimension of empathy, pharmacists were perceived to embrace the least of this attribute of the four sources. Therefore, while a reliable source of information, pharmacists may have to improve upon a humanistic aspect of their interaction with clients.

Several surveys show that pharmacist recommendations have a high acceptance rate by clients. In a 1995 American survey, pharmacists reported that clients bought recommended OTCs more than 80 percent of the time (Anonymous, 1995)\(^\text{107}\). In 1998, results from a telephone survey of 1,008 American adults found that 73 percent would take a pharmacist’s advice for an OTC product, even if the product differed from the one they had been using for years. As well, if the product recommended was not highly advertised, 70 percent of respondents still would accept the advice. If their pharmacist and friends/families had differing recommendations for an OTC product, 67 percent would choose the pharmacist’s choice. Further, 59 percent would buy the product recommended by a pharmacist, even if it was more expensive than the one they usually bought (Smith, 1998)\(^\text{108}\). Results from another American consumer survey showed that most consumers (98 percent) feel extremely or somewhat satisfied with OTC information given

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by pharmacists, and at times, more satisfied than when receiving such information from physicians (Gannon, 1995)\textsuperscript{109}

A systematic review shows that pharmacists are often perceived by laypersons as drug experts with limited knowledge on health issues, but customers are generally satisfied with their extended role in providing health advices [Anderson, 2004]\textsuperscript{110}. In Hong Kong where the culture is unique, local populations' expectation on the extended roles of community pharmacists may be raised to improve patient-oriented community health services.

Ried, 1999\textsuperscript{111} found the social skills of pharmacists to be more important to patients than was any technical expertise. In Sweden, positive interactions involving self-care matters occurred when pharmacists provided information, recommended better treatment alternatives, and demonstrated product uses (Hoog, 1994)\textsuperscript{112}. Research suggests that any professional advice received also appears to be accepted (Anonymous, 1995\textsuperscript{113}; Robbins, 1985\textsuperscript{114}).

Attention has also been called to the role played by pharmacists and shop attendants in fostering self-medication and medicine experimentation among the public. (Krishnaswamy, 1983\textsuperscript{115}; Logan, 1983\textsuperscript{116}; Shiva, 1985\textsuperscript{117}). In Hong Kong, western medicine community

\textsuperscript{109} Gannon K. Patients content with OTC information from R.Ph.s. Drug Topics 1990; Mar: 26-7.
\textsuperscript{116} Logan K. The role of pharmacists and over-the-counter medications in the health care system of a Mexican city Med. Anthrop., 1983; 13. 68-84.
pharmacists provide advice about medicines [Lee VW, 2003118; Lee SSC, 2004119; Cheng, 2005120; Chan 2006121] rather than addressing the clients’ wider determinants of health.

A survey was conducted amongst 300 consumers to identify and quantify the community pharmacist's involvement in the use of non-prescription/over-the-counter (OTC) medicine/self-medication in community pharmacies throughout South Africa. The major finding of this study was that a large majority of the participants agreed that community pharmacists play a positive role and add value. It was found that the main reason for visiting a specific pharmacy was the proximity of that pharmacy (Health Gesondheid, 2006)122.

2.1.6. a) Consumer’s attitude towards the role played by Pharmacists in OTC purchase

Asians and Africans show a high regard towards pharmacists as professionals. This view is best represented by a consumer’s statement ‘pharmacists are well educated in terms of pharmacy […] they understand medicines and indications well’, (Olsson, 2002)123 and a study

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from Japan showed about half of the interviewed general public (46.5%; n= 5188) view pharmacists as ‘drug experts (Hayashi S, 2003)\textsuperscript{124}

A certain degree of reliability is also cast on pharmacists by the public. In Japan, a majority expressed high and certain degree of reliability (87.8%; n= 5188) towards community pharmacists, while in Taiwan more than 80% believed pharmacists should provide drug counseling and could ensure safety in drug use (91.3%, 84.2%; n= 514) (Wen,2007)\textsuperscript{125}. In Nigeria, pharmacy is considered reliable and a source of genuine drugs (59.2%; n= 503) (Oparah, 2006)\textsuperscript{126}

The main factor found to influence the public's choice of OTC medicines was pharmacist recommendation. This is reassuring especially with increasing availability of potent medications without prescription and the increased potential for interactions (Bell 2000\textsuperscript{127}, Honig 1995\textsuperscript{128})

The role of pharmacists when appreciated by the consumers were also criticized by many based on the grounds that the pharmacists were not qualified to suggest the patients regarding medicines. Patients expressed fairly negative attitudes towards pharmacists making generic substitutions and were even more hostile to the idea that pharmacists should make therapeutic


substitutions. (Bradley, 1995)\textsuperscript{129}. Pharmacists in England have received especially harsh criticism regarding the profession's performance in the area of self-medication. (Anonymous, 1991\textsuperscript{130}; Anonymous, 1994)\textsuperscript{131}

The situation in Bombay was described by Kamat and Nichter (1998)\textsuperscript{132} where pharmaceutical companies provide incentive schemes to wholesalers, so that counter-pushing of some medicinal products could maximize profit for benefited retailers. The impact this had on the low-income public’s trust towards pharmacy was also noticeable through their description. It was stated that patients would go back to check with the doctor if a brand substitution was acceptable. The outcome was often that customers returned the substitute on the same day they bought it, saying the doctor told them not to accept it. The action of framing and displaying the signature pharmacist’s license certificate for practical purposes to meet rules from Indian government was reported; in fact, some pharmacy owners expressed experience in the retail business was far more useful than to have a pharmacy degree.

In the United States, Barnett and colleagues (1992)\textsuperscript{133} used disguised shoppers to evaluate the advice given on matters relating to OTC medicines. Pharmacy students posed as patients in 84 community pharmacies in Atlanta. Each student took turns posing as: (1) a man with a gastric ulcer who was bothered by constipation and was overusing laxatives, or (2) a man with high blood pressure who was experiencing chronic congestion (overusing nasal decongestants). Of the

\begin{footnotes}
\footnoteref{131} Anonymous. ITN checks up on how pharmacists sell Zovirax Pharm J.1994; 252:10.
\end{footnotes}
121 products recommended during the study, almost equal numbers were deemed satisfactory as unsatisfactory by the evaluators. The authors still felt that improvements had been made, based on the fact that more questions were asked of patients and directions were more commonly provided than in earlier studies. Just over 16% of the pharmacists advised the applicable patients that continued use of a nasal spray might be the cause of their congestion.

These pharmacy personnel have minimal formal education and little or no professional training. They recommend medicines which have dramatic effects as well as lucrative profit margins e.g., dispensing of anti diarrheal preparations with or without due emphasis on ORS. In the context of growing urbanization this issue of self-medication is even more serious because neither does these pharmacy personnel have time to explain nor the customers the time or awareness to question their advice. Medicines are mostly being dispensed without prescription (on consumer demand). These drug stores are quite commercial and have other items of general provision too. Similar business-like environment at pharmacies is also reported from India. (Vinay K, 1988)\textsuperscript{134}.

Medicines are mostly being dispensed without prescription (on consumer demand). These drug stores are quite commercial and have other items of general provision too. Similar business-like environment at pharmacies is also reported from India. Legal requirements for running such a drug store were compromised. These stores did not have a proper license and work force employed was neither well educated nor formally trained. Of those few who were trained majority were not present at the pharmacy location where they were officially registered as owners or employees. A study conducted in Sri Lanka demonstrates a similar pattern where

qualified pharmacists often own a chain of pharmacies, each of which they visit in turn at regular intervals (Ferguson 1981)\textsuperscript{135}

The Pakistan Pharmacy Act of 1967 clearly advocates supervised chemist trade and prescription of drugs by trained personnel. This law also requires the drug store to be certified and that certificate be clearly visible. Studies however show that the system in developing countries operates in a way that the shop is licensed in the name of the qualified proprietor, who seldom attends the shop, if at all (Fabricant, 1987\textsuperscript{136}; Greenhalgh, 1987\textsuperscript{137}). It has been noted that purchase of drugs and many drugs that can only be purchased with prescription in developed countries are OTC in developing countries. Also, lax medical regulation has resulted in the proliferation of counter fee drugs that are in high demand for the treatment of highly prevalent diseases (Shakoor, 1997)\textsuperscript{138}

Although a limited number (approximately 800) of individuals graduate as Bachelors of Pharmacy, the total number of retail and wholesale drug outlets in Pakistan are around 45,000-50,000 (Das, 1999)\textsuperscript{139}. The pharmaceutical industry plays a key role in promotion and sale of medicines. The total number of registered pharmaceutical companies in Karachi out of a total of 14,000 in Pakistan (Rasmussen, 1996)\textsuperscript{140}. Along with the common practices of self medication,

\textsuperscript{136} Fabricant S. i, Hirshhom, II. Deranged distribution, perverse prescription. unprotected use The Irrationality of Pharmaceuticals in the Developing world. Health Policy Plan., 1987:2,204-213.
\textsuperscript{138} Shakoor, O, Taylor RB, Behraus RH. Assessment of the incidence of substandard drugs in developing countries. Tropical medicine and International health 1997; 2: 839-845.
almost every drug store salesperson is illegally involved in the recommendation and sells of prescription only medicines in Bangladesh (Roy, 1997)\textsuperscript{141}.

2.1.7. Reported Side effects of OTC

It has been reported that almost 20\% of all drug-related admissions to a medical service resulted from the use of non prescribed medication (Caranasos, et al. 1974)\textsuperscript{142}. In the less developed countries, obtaining POMs or even antibiotics without medical supervision can mean putting patients’ health at risk. Drug safety issues, inappropriate treatment and increased microbial resistance are the most direct consequences. OTC cough and cold medications are associated with potentially serious side effects (Kernan, 2000\textsuperscript{143}; Cetaruk 1994\textsuperscript{144}; Lake 1990\textsuperscript{145}; Conway 1989\textsuperscript{146}; Rostagno 1996\textsuperscript{147}).

Edward Mills et al (2003)\textsuperscript{148} sought to determine the safety of 500 mg immediate release niacin, when healthy individuals use them as directed. 51 female and 17 male healthy volunteers (mean age 27 years SD 4.4) participated in a randomized placebo-controlled blinded trial of a single dose of an OTC, immediate-release niacin 500 mg (n = 33), or a single dose of placebo (n

\textsuperscript{142}Caranasos GJ, Stewart RB, Cluff LE. Drug-induced illness leading to hospitalisation. JAA'IA 1974; 228: 713- 7.
\textsuperscript{146}Conway EE, Walsh CA, Palomba AL Supraventricular tachycardia following the administration of phenylpropanolamine in an infant. \textit{Pediatr Emerg Care} 1989; 5:173-174
\textsuperscript{147}Rostagno C, Cacioli S, Felici M, Gori F, Neri Semeri GG Dilated cardiomyopathy associated with chronic consumption of phenidimetrazine. \textit{Am Heart J} 1996; 131:407-409
flushed (relative risk 35, 95% confidence interval (CI) 6.8–194.7). Mean time to flushing on niacin was 18.2 min (95% CI: 12.7–23.6); mean duration of flushing was 75.4 min (95% CI: 62.5–88.2). Other adverse effects occurred commonly in the niacin group: chills (51.5% vs. 0%, \( P < .0001 \)), generalized pruritus (75% vs. 0%, \( P = <.001 \)), gastrointestinal upset (30% vs. 3%, \( P = .005 \)), and cutaneous tingling (30% vs. 0%, \( P = <.001 \)). Six participants did not tolerate the adverse effects of niacin and 3 required medical attention.

Acetaminophen is one of the most commonly used drugs in Vicodin and the United States, (Kaufman, 2002)\(^{149} \) yet it is also an important cause of serious liver injury. The Acetaminophen found in Vicodin and thus causing side effects such as liver failure is the generic name of a drug found in many common brand name over-the-counter (OTC) products, such as Tylenol, and Prescription (Rx) products, such as Vicodin and Acetaminophen is an important drug, and its effectiveness in relieving pain and fever is widely known. Unlike other commonly used drugs to reduce pain and fever (e.g., non steroidal anti Inflammatory drugs (NSAIDs), such as aspirin, ibuprofen, and naproxen), at recommended doses acetaminophen does not cause adverse effects, such as stomach discomfort and bleeding, and acetaminophen is considered safe when used according to the directions on its OTC or Rx labeling.

However, taking more than the recommended amount can cause liver damage, ranging from abnormalities in liver function blood tests, to acute liver failure, and even death. Many cases of overdose are caused by patients inadvertently taking more than the recommended dose (i.e., 4 grams a day) of a particular product, or by taking more than one product containing acetaminophen (e.g., an OTC product and an Rx drug containing acetaminophen).

In 2004, FDA sent letters to every state board of pharmacy asking them to consider requiring labeling on the immediate container of Rx products containing acetaminophen that: (1) uses the term acetaminophen, not APAP, (2) instructs patients to avoid concurrent use of other acetaminophen containing drugs, (3) instructs patients not to exceed the maximum daily recommended acetaminophen dose, and (4) instructs patients to avoid drinking alcohol during prescription use. FDA was informed by the National Association of Boards of Pharmacy that, as of February 2008, no states had implemented regulations related to the request.

In December 2006, FDA issued proposed regulations for OTC labeling for acetaminophen containing products such as Vicodin to require inclusion of new safety information and that the container and outer carton identify acetaminophen when it is an ingredient.\textsuperscript{150}

Over-the-counter stimulants (phenylpropanolamine hydrochloride, ephedrine, pseudoephedrine, caffeine) are used widely as decongestants, anorectic agents, amphetamine substitutes, and "legal stimulants." Toxic effects may result from overdose, drug interactions, or diseases that increase sensitivity to sympathomimetic agents. The most important toxic effect of the a-adrenergic agonist phenylpropanolamine is hypertension, which may result in hypertensive encephalopathy or intracerebral hemorrhage. Toxicity of Over-the-Counter Stimulants (Paul \textsuperscript{151}; Pentel, 1984)\textsuperscript{152} Use of NSAIDs and aspirin, for example, are associated with an increased risk of adverse drug events, hospitalization and death, with the elderly being

\textsuperscript{150} Source:http://doihavealawsuit.com/lawyer-attorney/class-action-lawsuit/174-vicodin.html

\textsuperscript{151} Paul, \textit{JAMA} 1984;252:1898-1903

\textsuperscript{152} Pentel P Toxicity of over-the-counter stimulants. \textit{JAMA} 1984; 252:1898-1903
particularly vulnerable [Visser, 2002]. Some OTC medicines may also have severe interactions with prescribed medicines [Honig, 1998].

Joseph in a study in 2006 assessed the “real-world” risk of serious gastrointestinal (GI) toxicities, defined as perforations, ulcers and bleeds (PUBs) in a U.S. representative population that was using two commonly available over-the-counter (OTC) non-selective non steroidal anti inflammatory drugs (NSAIDs), naproxen or ibuprofen with or without concomitant aspirin usage. The data set contained 11,957 subjects on naproxen and 38,507 subjects on ibuprofen. Subjects taking both ibuprofen and aspirin had an odds ratio of 3.36 (2.36-4.80, P < .00001), while those on naproxen and aspirin had an odds ratio of 2.07 (1.23-3.49, P = .005) relative to those subjects on ibuprofen and naproxen mono therapy, respectively. Utilizing a national electronic medical record database representing patients seen predominantly in a primary care setting, this study has documented the "real-world" risk associated with the use of two common OTC NSAIDs, as well as the increased risk associated with concomitant aspirin use in this population.

The potential toxicities of cough and cold medicines vary with their composition. Many products contain multiple substances including a decongestant, cough suppressant, antihistamine, and/or antipyretic/analgesic. Pseudoephedrine and PPA are sympathomimetics that reduce nasal congestion by stimulating the α-andrenergic receptors on vascular smooth muscles.

Clinical toxicity presents with central nervous system (CNS) stimulation, hypertension, and tachycardia with ephedrine or pseudoephedrine ingestion, and bradycardia with PPA

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ingestion (Ceterauk, 1994\textsuperscript{155}, Lake C.R. 1990\textsuperscript{156}). CNS stimulation can manifest as extreme agitation, restlessness, insomnia, psychosis, and seizures. Serious complications after decongestant ingestions and/or overdoses include hypertension, tachycardia, bradycardia, seizures, stroke, and cerebral hemorrhage. (Glick 1987\textsuperscript{157}, Kase 1987\textsuperscript{158})

The true prevalence of OTC CCMs in pediatric illness might be underreported. Physicians might not consider the role of such medications in various presentations, such as apparent life-threatening events (ALTEs). Pitetti et al reported 13 out of 274 (5\%) patients presenting with ALTEs had evidence of OTC CCM use on toxicology testing. This raised concern about the potential role of OTC CCMs in ALTEs and led the authors to conclude that toxicology screening should be performed in all cases of ALTEs. (Pitetti RD, 2008)\textsuperscript{159}.

Ingredients of OTC CCM have also been linked to several pediatric deaths. During postmortem toxicology evaluation of children with unclear causes of death, OTC CCM ingredients were found. In these cases, OTC CCMs were used as directed or in order to induce side effects such as sedation or to cause intentional overdose. (Marinetti L, 2005\textsuperscript{160} & Boland DM, 2003\textsuperscript{161}).

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\textsuperscript{158} Kase CS, Foster TE, Reed JE, Spatz EL, Girgis GN Intracerebral hemorrhage and phenylpropanolamine use. Neurology 1987; 37:399-404
Cohen (2007)\textsuperscript{162} in her article showed “that of 307 unintentional overdoses leading to hepatotoxicity between 1998 and 2001; 25\% of these patients were taking more than one acetaminophen-containing product.” Other examples of unintentional acetaminophen overdose of OTC drugs was reported to the Institute for Safe Medication Practices (ISMP) of particular concern are the 27,000 accidental childhood acetaminophen overdoses reported annually by the American Academy of Pediatrics. Another study performed by Kirk et al. (2000)\textsuperscript{163}, involved pharmacy students who evaluated the comprehension of consumer-directed OTC medication information.

Over The Counter medicine has also been studied by Patel, Branck, and Arocha (2002)\textsuperscript{164}, in which they found that subjects of different cultural and educational levels make multiple errors in cognitive processes while comprehending procedural texts on pharmaceutical labels. The subjects in the study were from Canada and Kenya. Thirty mothers were instructed to read and interpret labels to be used for their children. The researchers took notes of the outcome and observed that when the subjects put into practice their interpretation of the dosage given, 3 out of 15 Kenyan subjects and 2 out of 15 Canadian subjects did not follow the correct dosage provided through the literature of the label. Another study included 878 participants from Kenyan and Canadian patients were given OTC literature to interpret and a comprehension score

was calculated based on eleven questions obtained from the participant response form. This study demonstrated that OTC medicines were difficult to interpret by 72% of the subjects.

OTC drugs pose particular drug safety concerns as they are dispensed and used without the direction of a health care professional. Patients may combine OTC drugs with their prescription medicine, potentially causing drug interactions if the substances are incompatible. Patients may also inadvertently take multiple OTC drugs containing the same active ingredient, which could lead to an overdose or increased side-effects. Self-medication also has advantages for healthcare systems as it facilitates better use of clinical skills of pharmacists, increases access to medication and may contribute to reducing prescribed drug costs associated with publicly funded health programmes (Hughes 2001)\textsuperscript{165} However, increasing availability of non-prescription medicines may encourage patients to believe that there is a drug treatment for every ailment. Furthermore, the use of such products may delay/mask the diagnosis of serious illness (Hughes 2003)\textsuperscript{166} with increased risks of interactions and adverse reactions and of self-treatment being undertaken when medical aid should have been sought. (Hughes 2002)\textsuperscript{167}

Studies in children of the immediate, (Clemens CJ 1997) short-term (Hutton N, 1991) (within 48 hours), and long-term (Taylor JA, 1993) (after 72 hours) effects of cough and cold preparations showed no significant difference between OTC medications and placebo in the reduction of cough.


The US National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance program reported that OTC CCM preparations were responsible for 7091 visits to emergency departments (EDs) during 2004 and 2005 in children younger than 12 years old. This represented almost 6% of total ED visits related to medication. Of these cases, 66% were due to unsupervised ingestion. A quarter of cases were due to properly administered medications with undesired outcomes. Eight times more children presented with effects of medication errors related to OTC CCMs compared with other medications. While children aged 2 to 5 years represented the largest group in this study, children younger than age 2 had the highest rate of adverse reactions (Schaefer MK, 2008)\textsuperscript{168}. Two earlier case series reported 4 deaths in children younger than 9 months of age that were best explained by OTC CCM ingredients. (Gunn VL, 2001)\textsuperscript{169}.

A recent review of unexplained infant deaths in Arizona yielded 10 cases linked to OTC CCM use. Toxicology was available for only 21 of the 90 children in the review, and the study results might underestimate the link. Five of these children came from non–English-speaking families, and OTC CCM use was prescribed by a physician in one other case. (Rimsza ME, 2008)\textsuperscript{170}.

More recent data regarding OTC CCM and pediatric deaths were published in 2009. An expert panel of pediatricians and toxicologists published a report after reviewing deaths due to


OTC CCM use in patients younger than 12 years of age. Five sources of data were looked at including the medical literature, the FDA database, and manufacturers’ data. The panel found that of 189 cases, 118 were judged to be possibly, likely, or definitely related to OTC CCM ingredients. Of the 118 cases, 103 involved nonprescription drugs, with 88 involving overdose. The authors found several factors associated with the fatalities: age younger than 2 years, use of the medication for sedation, use in a day care setting, combining 2 or more medications containing the same ingredient, failure to use a measuring device, product misidentification, and use of products intended for adults. Finally, review of the information showed that 6 of the children died after an attempt to sedate them, 3 were cases of abuse, and in 10 cases homicide was suspected. (Dart RC, 2009)  

Consequences of inappropriate OTC drug use include deprived therapeutic benefits, accidental overdose effects, adverse side effects, and economic waste. Physical risk from misuse can be high. Adverse reactions and accidental overdose are responsible for drug induced illnesses which can require hospitalization and in some cases result in death (Silverman and Lee, 1974; Caranasos et al., 1974; Buchanan et al., 1976).

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2.1.8. Level of awareness about side effects of OTC

OTC drugs, easily available to potential consumers, may result in problems if used in higher dosages than recommended, in combination with other drugs, or when based on an incorrect self-diagnosis. Young consumers may lack the ability to judge the potential benefits and risks which may result in damaging and fatal injuries, while some intentionally use the medicines for recreational purposes.

A survey study was done by Elaine Cham, 2002\textsuperscript{175} among 213 subjects to determine basic knowledge about and use of over-the-counter (OTC) pain medications among patients seen in the emergency department (ED) and found that 143 (67\%) reported having used some form of nonsteroidal anti-inflammatory drug (NSAID) and 127 (60\%) had used acetaminophen products recently. Women were more aware of toxic interactions and gastrointestinal (GI) irritation related to these medications. Ibuprofen use correlated with age (younger individuals used more) and having no primary physician (those without a physician used less). Knowledge about GI effects correlated with age, sex, and education. Knowledge about renal and hepatic problems correlated with age and education. The study concluded that many were ill informed about their use and side effects.

Generally, teenagers are less familiar and have less experience with products as compared to older consumers (Tamara, Dhruv and Terry, 1997)\textsuperscript{176}. The teenage years are also viewed as the most critical phase for the acquisition of consumption-related orientations, both desirable and undesirable (Moschis and Cox, 1989)\textsuperscript{177}. Besides, the consumption-related

\textsuperscript{175} Elaine Cham, Louise Hall, Amy A. Ernst, MD, Steven J. Weiss, MD Awareness and Use of Over-the-Counter Pain Medications: A Survey of Emergency Department Patients, South Med J. 2002; 95(5).


knowledge learned in early life may be carry over to adulthood. It is thus important to understand how those in this age group learn to become consumers of OTCs, not only to make better consumer decisions at present but also in their future consumer roles.

**Consumer’s attitude about OTC drugs side effects**

People believe that only safe medicines are permitted to be sold without prescription and that OTC medicines do not usually have serious side-effects. *(Hughes 2002)*

To assess the frequency and indications for over-the-counter (OTC) nonsteroidal antiinflammatory drug (NSAID) use and to what degree the public is aware of their side effects, two surveys totaling 9062 respondents were performed of the American public. The Roper survey, conducted in 1997, and the National Consumers League (NCL) survey, conducted in December 2002, was intended primarily to assess the public's use of and attitudes toward NSAID and OTC analgesics. The results showed that forty-six percent of exclusive OTC users believed OTC were safer, while 56% of exclusive users of prescription NSAID believed they were safer. Sixty percent and 29% of exclusive OTC users were neither aware of nor believed they were at risk for side effects from NSAID, respectively *(C. Mel Wilcox)*

The study by Wilson KM, 2010 evaluated misconceptions and knowledge gaps about OTC side effects, risks, and interactions among adolescents attending a hospital-based clinic. Adolescents aged 14 to 20 years presenting to an outpatient clinic were surveyed using a computer-administered instrument. Results proved that most adolescents use OTC analgesics,

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but many were confused about generic and brand name forms. There were also significant knowledge gaps about OTC use, side effects, and contraindications, especially for acetaminophen. Researchers suggested that clinicians should be aware of the potential for OTC medication misuse by adolescent patients.

Joseph Thomas (2002)\(^{180}\) conducted a telephone survey of an age-stratified U.S. random sample of 535 persons at least 40 yr old, who used an OTC NSAID for 4 of the previous 7 days, and a matched comparison population of 1068 persons who used no NSAID within the previous 30 days. Results proved that the most commonly used OTC NSAID was aspirin (alone or in combination compounds). Prevention of myocardial infarction or stroke was the most common reason for use (43.2%), followed by all forms of pain relief (44.2%) and relief of arthritis symptoms (24.5%). NSAID users were twice as likely as nonusers to report GI side effects (19.6% vs 9.5%, \(p = 0.0001\)), and more than twice as likely to use an OTC GI medication when they had GI symptoms (46.7% vs 20.8%, \(p = 0.001\)).

Research was carried out to investigate the general public's (n=1000) opinion and perceptions of OTC medicines, with a focus on their knowledge and opinion of the misuse/abuse of such preparations. The survey revealed that general public in Northern Ireland was highly aware of the abuse potential of some of OTC drug (Wazaify, Mayyada M. 2003)\(^{181}\)

Self-medications in a country with low literacy level like Bangladesh is very important where prescription medicines are freely available. This may pose serious risks related to inappropriate and irrational personal use of medicines. Like all other developing countries,


irrational and inappropriate use of medicines is very common in Bangladesh (Ronsmans, Islam, Bennish, 1996)\textsuperscript{182}

Before taking a drug, consumers should read, understand and follow drug instruction according to drug information present on the drug leaflet. Thus, understanding the drug information written on drug leaflet is also an important step to achieve drug therapy (Holt et al., 1990)\textsuperscript{183}.

A Canadian study reported that 62 percent of participants \textit{always} read labels; 16 percent \textit{often} read them; 9 percent were on record as \textit{sometimes}; 6 percent as \textit{seldom}; and 7 percent \textit{never} read them (Decima, 1990)\textsuperscript{184} Comparing Canadian and American national consumer surveys suggests that most do not read full information appearing on the package of an OTC product when they buy it for the first time. For example, only 40 percent of Canadians read active ingredients, followed by the dosage level (34 percent), the symptom it treats (26 percent), possible side effects (23 percent), directions for usage (18 percent), and warnings (10 percent) when they buy a product for the first time. (Decima, 2002)\textsuperscript{185} American data showed that the proportion of readers in each section were even lower than the Canadian statistics – directions for usage (19 percent), dosage level (16 percent), symptom it is used for (12 percent), possible


\textsuperscript{183} Holt, G.A., J.D. Hollon, S.E. Hughes and R. Coyle. 1990. OTC labels: can consumers read and understand them?. American Pharmacy NS 30 (11): 51-54.

\textsuperscript{184} Decima Research. Attitude, Perceptions and Behaviour Relating to Ethical Medicines: A Research Report to the Department of National Health and Welfare. Ottawa: Drugs Directorate, Health Protection Branch, Department of National Health and Welfare; 1990

\textsuperscript{185} Decima Research. OTC habits and practices: the attitudes and beliefs about over-the-counter medicines. Ottawa: Drug Information and Research Center (DIRC); 2002
side effects of usage (10 percent), and warnings (7 percent). (NCPIE Report, 2002) In the American survey, researchers also found that more Americans would read directions for usage (22 percent) and dosage level (25 percent) when they take the medicine for the first time, rather than when they buy it for the first time.

Understanding the leaflet content could result in fully complying with the drug direction (Ciociola et al., 2001). Leaflet content should be simple, easy and understandable to lay consumers so that they can correctly follow the instruction (Farley, 1997; Nordenberg, 1999). Food and Drug Administration (FDA) of many developed countries require that drug leaflet must pass understanding test on consumers (Dickinson et al., 2001; Greenburg, 2001) while in some countries, this test is not officially required. There are several studies which are concerned with consumer’s understanding. It was shown that patients had difficulty in understanding drug information on drug leaflets and needed clearer and easier instructions (Hermann et al., 1978; Miselli and Tognoni, 1990; Stichele et al., 1991) Furthermore,

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some patients misunderstood and misinterpreted drug instruction about dosage regimen (Holt et al., 1992). These reports indicated an inadequacy of understanding among consumers.

In the United States, Over the Counter drug labels are required to be understood by consumers who possess a functional level of the English language (Adkins & Curus, 2009). Weiss (2001) in his article “Health Literacy: An important issue for communicating health information to patients,” explains that health literacy refers to an individuals’ ability to read, understand, and use the information necessary to obtain adequate health care information in written form it requires some degree of health literacy. Limited health literacy is a wide spread problem in all nations and it is mostly related to efficient readings skill. The inability to speak English is significantly relative to healthcare (Levy & Royne, 2009).

2.1.9. Legal protection through Consumer Forum/Council/Act

2.1.9.1. Definition of Consumer

Definition of Consumer as defined in the Consumer Protection Act, 1986, 'Consumer' means any person who -

- buys any goods for a consideration which has been paid or promised or partly paid and partly promised, or under any system of deferred payment and includes any user of such goods other than the person who buys such goods for consideration paid or promised or partly paid or partly promised, or under any system of deferred payment when such use is made with the approval of such person, but does not include a person who obtains such goods.

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goods for resale or for any commercial purpose; or hires or avails of any services for a consideration which has been paid or promised or partly paid and partly promised, or under any system of deferred payment and includes any beneficiary of such services other than the person who hires or avails of the services for consideration paid or promised, or partly paid and partly promised, or under any system of deferred payment, when such services are availed of with the approval of the first mentioned person; \(\text{(Explanation, - For the purposes of sub-clause (i), "commercial purpose" does not include use by a consumer of goods bought and used by him exclusively for the purpose of earning his livelihood, by means of self-employment.}\)

2.1.9.2. Consumer Rights

In order to safeguard consumer interest, 6 consumer rights were initially envisioned by consumer rights activists of the West, namely:

- Right to Safety
- Right to Information
- Right to Choice
- Right to be Heard
- The Right to Redress
- The right to consumer education

2.1.9.2. a) Right to Safety

Consumer right to safety is as vast in its purview as the market reach itself. It applies to all possible consumption patterns and to all goods and services. In the context of the new market economy and rapid technological advances affecting the market, the right to safety has become a pre-requisite quality in all products and services. For e.g. some Indian products carry the ISI
mark, which is a symbol of satisfactory quality of a product. Similarly, the FPO and AGMARK symbolise standard quality of food products. The market has for long made consumers believe that by consuming packaged food or mineral water, consumers can safeguard their health. This notion has been proved wrong time and again due to rampant food adulteration in market products. Right to food safety is an important consumer right since it directly affects the health and quality of life of consumers.

Earlier, the interpretation of the right to safety was limited to electronic products and other such products. Now, its definition has expanded a lot to include safety aspects of new technologies like GM food, food labelling, chemical ingredients in food products etc. In today's scenario of globalisation, consumers have no control over where the products or commodities they use, come from. For instance, the chocolates or syrups we consume may be manufactured in countries as far as the U.S. or Australia. Consumers in India would have no control over or knowledge of the manufacturing practices of those countries and will have to rely completely on import regulations of the Indian government and food labelling. This makes the consumer right to safety a very important and critical issue for consumers.

2.1.9.2. b) Right to be Heard

The right to be heard means that consumers should be allowed to voice their opinions and grievances at appropriate form. For e.g. if a consumer been cheated in the market place or deprived of the right quality of service, their complaint should be heard and given due attention by the authorities. Consumers should also have a right to voice their opinion when rules and regulations pertaining to them are being formulated, like the recent amendments in the Consumer Protection Act. The right to be heard holds special significance in the Indian context because Indian consumers are largely unaware of their rights and passively accept their violation. Even
when they have legal recourse, they prefer not to use it for fear of getting embroiled in legal complexities.

To allay consumer fears and to allow them to express their views and grievances, consumer forums have been in existence in India for a long time. Consumers have been approaching these forums and consumer NGOs regarding their problems and complaints.

2.1.9.2. c) Right to redress

Competition is the by-product of the market economy. Every day, manufacturers are discovering newer ways of cheating and duping consumers. Unscrupulous market practices are finding their way into consumer homes, violating consumer rights and jeopardising their safety. It is to protect consumer interests that consumers have been given the right to obtain redress. In India, we have a redress machinery called Consumer Courts constituted under the Consumer Protection Act (1986), functioning at national state and district levels. But it has not been made complete use of under due to lack of awareness of basic consumer rights among consumers themselves.

While in the developed world, right to redress is perhaps the most commonly exercised consumer right, in developing countries, consumers are still wary of getting involved in legal redress system. There are consumer courts in India where any consumer can lodge a case if s/he thinks he or she has been cheated. The details of how to lodge a complaint have been explained elsewhere in the manual

2.1.9.2. d) Right to Consumer Education

Consumer education empowers consumers to exercise their consumer rights. It is perhaps the single most powerful tool that can take consumers from their present disadvantaged position to one of strength in the marketplace. Consumer education is dynamic, participatory and is mostly
acquired by hands-on and practical experience. For instance, a woman who makes purchase decisions for the household and does the actual buying in the marketplace would be more educated about market conditions and ‘best buys' than a person who educates himself about the market with the help of newspapers or television. Also, today, it is not just the market or products that a consumer needs to educate him about but s/he also needs to know about company profile, government policies and introduction of new technology.

Market influences have grown so much that not just wholesale and retail sellers but even medical practitioners are falling prey to their pressures. The pharmaceutical industry is one such example. India, with its 1 billion population and largely uneducated consumers, is a very lucrative market for this industry. The pharmaceutical industry, to boost its sales, offers free samples of medicines, freebies, and even free luxury holidays to physicians to influence them to use their brands and give them preference over other brand names. There have been many instances when drugs banned in countries like US, have been prescribed to Indian consumers and are readily available as over-the-counter drugs. It is a sad example of gross violation of consumer trust by medical practitioners. This situation is rampant not just in rural areas but also among educated urban consumers. The reason why the market, in connivance with physicians, is able to exploit consumers is that Indian consumers are not aware of the prevailing situation and do not keep themselves abreast with latest developments taking place around them. Consumer education can play a crucial role in protecting consumers against such dangers. In the Indian context, sustainability and traditional knowledge can play a vital role in empowering consumers but consumers are unable to connect to their knowledge base. Consumer education can rejoin the broken link and make traditional knowledge accessible to consumers again. Some sources of
consumer education are past experiences of consumers, information dissemination by
government agencies and NGOs, classroom teaching by teachers and informal lessons by
parents.

2.1.9.3. Regulations

The major legislation for pharmaceutical regulation is the *Drugs and Cosmetics Act, 1940* 
(DCA) and its subordinate legislation, the *Drugs and Cosmetics Rules, 1945* (DCR). Drug 
(Prices Control) Order, 1995, Drugs (Magic Remedies) Objectionable Advertisement Act, 1954 
and Pharmacy Act, 1948 are other regulations which have a bearing on the pharmaceutical 
business in India.

The legislations apply to the whole of India and to all categories of medicines (e.g., 
allopathic, ayurvedic, siddha, unani and homeopathy.), whether imported or manufactured in 
India. The legislation is regulated by the Central Government (*Ministry of Health & Family 
Welfare*) in New Delhi, which is responsible for its overall supervision and enforced by State 
Government through its *Food and Drug Administration* (FDA).

The office of the Drugs *Controller General of India* (DCGI) has the primary 
responsibility for approving new drugs, molecules and standards, Vaccines & Sera, new usage 
and claims, new method of administration, clinical research and trials, introductions of a new 
unique formulation and granting import and export licences. It oversees the activities of the 
*Central Drugs Standard Control Organization* (CDSCO). The DCGI also exercises control over 
medical devices imported or manufactured in India.

However, power to provide manufacturing and selling licences - which are the two main 
stages required to manufacture and sell a drug - belongs to each individual State Government
through its *Food and Drug Administration* (FDA). These Food and Drug Administration’s (FDAs) also carry out enforcement of the DCA and the DC$^{199}$.

**Drugs & Cosmetics Act**

The Drugs and Cosmetics Act 1940 is a central legislation, which regulates the import, manufacture, distribution and sale of drugs and cosmetics in the country. The main objective of the Act is to ensure that the drugs available to the people are safe and efficacious and conform to prescribed quality standards and the cosmetics marketed are safe for use. The Drugs Act was enacted in 1940 in pursuance of the recommendations of Chopra Committee constituted in 1930 by the Government of India. The Act received the assent of the Governor General on 10th April 1940 and thus became a statute. The Drugs Rules were promulgated in December 1945 and the enforcement of these statutes started in 1947. The Drugs Act, as enacted in 1940, has since been amended several times and is now titled as Drugs and Cosmetics Act. The Rules have also been amended from time to time to meet the needs of the times and to make good any deficiencies noticed during the implementation.

The very definition of ‘Drug’ under the Drugs & Cosmetics Act covers a wide variety of therapeutic substances, diagnostics and medical devices. It thus requires an adequate multidisciplinary expertise, which should be available with regulatory agencies, especially at the central level. Moreover, the standards of safety, efficacy and quality of therapeutic products are becoming ever demanding. Therefore, regulatory capacity has to become world class. Under the Constitution of India, ‘Drugs’ being a concurrent subject, the responsibility of enforcing the various provisions of the Act vests with the Central Government and the State/UT Governments. The roles of Central & State Governments are well defined. The Ministry of Health and Family

Welfare, Government of India constituted an Expert Committee under the Chairmanship of Dr. R.A. Mashelkar, Director General of CSIR to undertake a comprehensive examination of drug regulatory issues, including the problem of spurious drugs on January 27, 2003. The Committee noted that India has reasonably well drafted legislations, namely, Drugs and Cosmetics Act, which was enacted in 1940, and Drugs and Cosmetics Rules, which were drafted in 1945. These legislations define most of the above-mentioned functions but it is the enforcement at several levels that has not been consistent and uniform because of the multiplicity as well as the variable quality of enforcement authorities.

The restructured Central Drug Administration should have 10 main Divisions at the headquarters manned by adequately trained manpower. Each of these divisions may have several sections depending upon the scope of the activities of the respective division. These divisions could be named as:

1. Division for Regulatory Affairs & Enforcement
2. Division for New Drugs & Clinical Trials
3. Division for Biological & Biotechnology Products
4. Division for Pharmacovigilance
5. Division for Medical Devices and Diagnostics
6. Division for Imports
7. Division for Organizational Services
8. Division for Training and Empowerment
9. Division for Quality Control Affairs
10. Division for Legal and Consumer Affairs
The Committee observed that in India, because of numerous licensing authorities (State/UT’s), the implementation of drugs laws has been weak and non-uniform even after 56 years of enforcement. It is well established that the regulatory infrastructure in many States is below par, while it is functioning better in some. This has resulted in lack of adequate confidence among the consumers and level playing field for industry. The Committee observed that the issue of non-uniformity of enforcement at the state level was serious and needs to be addressed immediately. The Committee records that there should have been a single agency to regulate the manufacture and quality control of drugs in the country and that it should be done centrally.

**Over The Counter Drugs (OTC)**

As per the Drugs and Cosmetics Act and Rules, there is no separate category of drugs called OTC drugs. Currently those drugs, which are not covered under Schedule H, or G and their formulations (except their products for external applications) can be called as OTC drugs. However, all these need to be stocked, distributed and sold through premises licensed for sale, except for those, which have been specifically exempted by inclusion in Schedule K of D&C Rules. There is a need to improve the access to household medicines and products, which provide hygiene, to large masses in the interest of preventive health.

**Recommendations**

The Committee recommends the following:

a) Schedule K should be reviewed comprehensively. Products, which by virtue of their long usage and/or nature of their application (e.g. substances used for household cleaning and disinfectants generally used in a diluted form and not meant for direct application on human skin) could be considered for inclusion in the exempted category under schedule K to further facilitate their easier access to the public at large. Other categories / drugs, which have been
reviewed by an expert, sub-committee of DTAB and recommended for inclusion in Schedule K are calcium preparations without vitamins, antiseptic lotions, medicated mouth washes/rinses, psyllium and its preparations, cough and cold preparations without antihistamines and drugs included under NDPS Act.

b) Schedule H should be reviewed on an ongoing basis to add or delete products from the schedule depending upon their usage and safety profile.

c) A mechanism should be set up to review the list on a periodical basis. This should enable bringing in sufficient flexibility in the system on one hand and promoting sales and distribution of desirable products without in any way compromising on quality of the product on the other hand.

**Action by the Consumer and other Professional Associations**

There is an urgent need for an awareness campaign to educate the consumers and the medical and paramedical professionals. The Committee, in particular, recommends that the Consumers and health professional/associates should play an active and visible role to create awareness about the hazards of spurious drugs. They should undertake campaigns at the national level to educate the public on the ways and means of detecting spurious drugs and the advantages of purchasing from licensed sources with valid cash memos.

**Consumer Court**

A consumer court is a tribunal consisting of various judicial officers specially set-up for consumer complaints and malpractice reporting. In India consumer courts are set up in almost every region to attend consumer complaints and resolve them accordingly.
Law suits filed against pharmaceutical companies globally

In the largest settlement to date between a drug company and the federal government, GlaxoSmithKline would pay $3 billion to settle civil and criminal claims related to its illegal marketing practices for several drugs. Avandia, one of the pharmaceutical company’s most widely distributed drugs, was found to increase the risk of heart attacks in some patients. Rather than modifying the drug label to include an increased warning for heart attacks, or voluntarily recalling the drug, GlaxoSmithKline attempted to suppress an article that linked Avandia to the increased risk of heart attacks. Other controversial GlaxoSmithKline products include: Paroxetine (the anti-depressant with a black-box warning - the highest warning given out by the FDA) and Ribena (the fruit drink which falsely claimed to possess high levels of Vitamin C). GlaxoSmithKline was also currently fighting claims of cheating the United States Medicaid program200.

The Prilosec class action lawsuit was filed on May 29, 2009 in the U.S. District Court for the Southern District of Ohio against Proctor & Gamble and AstraZeneca PLC. The complaint alleges that the drug makers knew about the Prilosec food poisoning risk, as the drug reduces bacteria-fighting acid in the stomach, but they failed to adequately warn consumers. The named plaintiff in the Prilosec lawsuit is Thomas Mitchell, of Powell, Ohio, who started taking Prilosec OTC in July 2008. Mitchell claims that while taking the drug, he suffered from food poisoning symptoms that required medical treatment at least twice. According to the complaint, although the drug makers knew that Prilosec side effects decreases the amount of stomach acid, which has a negative effect on the stomach’s ability to destroy harmful bacteria when it is first ingested, they mislead consumers and indicated that users could continue to eat the foods they enjoy. After

AstraZeneca lost patent protection in 2002, generic forms of the drug became available. The drug maker enhanced and repackaged Prilosec as Nexium (esomeprazole magnesium), which works as much the same way. Nexium sales exceeded $5 billion during 2008.

On the 23rd of January 2012, a federal judge ruled that the drug maker Johnson & Johnson, had to defend against lawsuits charging it failed to properly warn that its over-the-counter Motrin pain reliever can cause Stevens-Johnson Syndrome and a deadlier form of the disease known as Toxic Epidermal Necrolysis. The judge refused to dismiss two lawsuits brought by parents who claim their children were harmed. The labeling for over-the-counter versions of Motrin - for adults and children - lists possible reactions, but neither disease is mentioned specifically. The diseases can cause blindness, massive skin loss, blisters and burns, massive scarring and damage organs. When the FDA scoured its database, the agency found 49 reports of SJS and TEN related to Motrin from 1975 through 2005. After discovery began for the lawsuits, J&J’s McNeil Consumer Healthcare unit produced 117 adverse event reports, and 87 were received prior to June 2009, just before each child was given Motrin201.

2.2. Ancillary findings

i) a. Source of information about OTC

During an illness episode, individuals commonly seek information and advice from a lay referral or therapy management group. This group affects self-diagnosis and treatment by contributing knowledge gained through experience, and by sharing of medications. Maintaining wide and active network becomes especially important for low income and uninsured individuals whose access to formal medical care is limited by financial constraints. In these cases, word of mouth information about effective self-care measures or about sources of free or reduced rate of

201  Pharma Blog » 2012 » January » 23  J&J Must Face Lawsuits Over OTC Motrin Labeling  

Family/parents, friends, neighbours, old prescription given in previous consultation and previous experience used as influential sources of information for self medication [Lau,,1995]203. Sources of self-medication drugs are many including: medicine cabinet at home or left-over past prescribed drugs; sharing of drugs with friends and relatives; pharmacies, traditional medical practitioners; family reserves etc, (Atakouma, D.Y., et al.,1999204; Jaquier, F., Buclin, T., and Diezi, J., 1998205; Chambers et al, 1997206; Vilarino et al, 1998207].

Whether one lives in a developing country or in a developed one, the sources of information are similar. A person may seek advice from ‘an older person in your household who possesses the knowledge of simple herbal remedies for common illnesses’ (Nepal, 2002) or with a pharmacist because they can ‘provide a good help to assess the symptoms’ and ‘spend time explaining how to use the medication properly’ (Brazil 1997, Singapore 2005). Or one may purchase an OTC medicine ‘based on a previous medical recommendation’ (Mexico, 1999). Product labels are also a good source of information for the consumer and should always be easily accessible. In China for example, 70% of the consumers select the OTC medicine through reading the specifications before purchase.

Television advertising appears to have a limited impact with respect to overall non-prescription medicine use: in Brazil (1997), 81% of consumers disagreed with the statement: “I customarily purchase medicines advertised on TV”. In Italy, between 1977 and 1987 – a period known in Europe for its large increase in television advertising, visits to physicians increased by 20% while the use of OTC medicines increased by only 2%. There were similar results in all the major European countries.

b. Purchase of Prescription-Only Medicines (POMs) without a Valid Prescription / illegal selling of POMs in India

Although it was not always the case in the countries this review looked into, there was clear references for the illegal selling of POMs to patients by community pharmacies in India, Africa (Kamat, 1998) and Taiwan (Wen MF, 2007) In the review ‘Pharmacy in Nigeria’ it was stated that although by law pharmacies and licensed drug outlets could only provide POMs against a valid prescription, poor enforcement by the responsible authority meant patients could still buy them without a valid prescription (Alo A., 2006)

Almost every drug store salesperson is illegally involved in the recommendation and sells of prescription only medicines in Bangladesh (Roy, 1997). Self-medications in a country with low literacy level like Bangladesh is very important where prescription medicines are freely available. This may pose serious risks related to inappropriate and irrational personal use of medicines. Like all other developing countries, irrational and inappropriate use of medicines is

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very common in Bangladesh (Ronsmans, Islam, Bennish, 1996). Recent study showed that about half of the antibiotics were sold without any prescriptions, and even ordinary people without any knowledge of medicine asked the drug seller for specific antibiotics (Mamun, Tabassum, 2006).

The likelihood of POMs being dispensed without prescription in some African countries was also mentioned in qualitative interviews with practicing pharmacists. The authors also brought up whether dispensing from a prescription stood as a guarantee, when even the qualification of the prescriber was not clear (Viberg N, 2007). It was not uncommon for patients to obtain antimicrobials without a prescription in India. These transactions by pharmacy attendants might only involve mentioning of the name or showing an old sample of the drug, and involves no presentation of symptoms.

Poor enforcement of governmental regulations was a clear reason why such situation happened. Nevertheless, the lack of knowledge about the correct use of medication was demonstrated to be severe in India among the public as well as pharmacy attendants. Pharmacy attendants often sold incomplete courses of antibiotics to the public. Unused or left-over medicines were also presented to the pharmacies by patients, in order to find out what they could be used for beyond the original recommendation (Kamat, 1998). There are reported sellings of POMs including antibiotics without presentation of valid prescriptions in some countries (Alo A,

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The strict control by law is believed to have prevented such happening in the developed countries.

**ii) Fake, Counterfeit and sub standard Drugs**

A 2003 Scrip report estimated that 15 to 20% of the medicines sold in the country are counterfeits\(^ {217} \). A case study reported in a 2001 conference showed the following percentage (out of 125 tracer medicines) that failed quality testing: 6% from the public sector, 12.7% from the private sector; and 0% from NGOs (Garg, 2001)\(^ {218} \). In 2001, Lancet reported that, according to WHO statistics, India produces as much as 35% of the fake and substandard drugs in the world. A powerful group of manufacturers have taken over much of the production during the past three years. It is reported that these counterfeit drugs are manufactured mostly in the northern states; but these fake drugs are widely available throughout the country.

India was among the six countries that participated in a drug quality study which collected a total of 71 samples of the antituberculosis drugs isoniazid (INH) and rifampicin (RMP) as a single entity or a fixed-dose combination (FDC) (see Multi-country studies). Overall, 10% (4/40) of all samples obtained from all six countries, including 13% (4/30) RMP were substandard, containing < 85% of stated content. More FDCs, 21% (5/24), than single drug samples, 13% (2/16), were deemed substandard (Laserson, 2001)\(^ {219} \).

The Organization of Pharmaceutical Producers of India (OPPI) suggested measures such as increasing consumer awareness, appointing officers in each state’s regulatory authority who


\(^{217}\) Scrip World Pharmaceutical News 2003, April Issue


would be responsible for issues concerning fake drugs, design registration, copyright litigation, inspection and control of sources of chemical supplies, imposition of heavy penalties on manufacturers of counterfeit drugs, enactment of a law similar to India’s Prevention of Terrorism Act, and constant vigilance by companies\textsuperscript{220}.

In summary, the available evidence appears to indicate that consumers do indeed distinguish differences between OTC and prescription medicines. By extension, a concern appears to exist whereby the public may not consider medicines available without prescription as full-fledged ‘medicines’, ones that require a level of vigilance during use. Location of sale may be a factor in the development of such perceptions. Impressions held of OTC medicines may be important pre-determinants of actual behaviour, where failure to consider such agents as important medicines requiring due care, could expose the public to important drug-related risk.

\textsuperscript{220} Scrip World Pharmaceutical News 2003, April & August Issues.