International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 4 July-Aug 2021, pp: 1419-1426 www.ijprajournal.com ISSN: 2249-7781

Drugs Used Primary Treatment and OTC Products: Pharmacy practice

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Date of Submission: 05-08-2021 Date of Acceptance: 21-08-2021

ABSTRACT

Background :

The over _ the _ counter (OTC) medicines it's defined as the selection and use of medicines by individuals (or a member of the family) without a prescription from a health professional to treat self recognized or self diagnosed conditions or symptoms , Non steroidal anti inflammatory drugs (NSAIDs) are common medications used by the general due to their anti inflammatory and analgesic properties.

Over – the- counter (OTC) NSADs comprise several drugs that may be purchased without a prescription . These are often over- utilized by the general population due to their accessibilityhealth practitioners are not needed and relatively low cost. The active role of the patient in his or her own health care .

_ potential risks of self medication practice include:

Incorrect self diagnosis ,ineffective treatment may result progression of disease , delays in seeking medical advice when needed , infrequent but severe adverse reactions , dangerous drug interaction , incorrect manner of administration , incorrect dosage, incorrect choice of therapy. Some of the important dangers related to self medication practices , particularly : polypharmacy and drug interaction.

Conclusion : the extent of self medication among the elderly who participated in in the study decreased between 2006 _ 2010 . But the use of medicines that offer risks to health was still reported. Thus the findings reinforce the importance of monitoring , evaluating and continuously educating the elderly about risks and benefits of drug consumption particularly over – the – counter medicines.

Keyword : self medication (OTC) Aged drug utilization inappropriate prescribing pharmacoepidemiology cohort studies.

I. INTRODUCTION

Drug Used Primary Treatment and OTC Products

Over-the-counter (OTC) drugs are medicines sold directly to a consumer without a prescription, from a healthcare professional, as compared to prescription drugs.In many countries, regulatory agencies select the OTC drugs to ensure that they are safe and effective when used. OTC drugs are usually regulated by active pharmaceutical ingredients, not the final products. By regulating APIs governments allow manufacturers freedom to combinations of ingredients or formulate ingredients into proprietary mixtures. Self-medication has an important role to play in healthcare. With improvement in people's general knowledge, education and socio- economic status, self-medication has been successfully integrated into many health care systems throughout theworld. Self-medication products are those that do not require a medical prescription and that are produced, distributed and sold to consumers. Self-medication with OTC drugs responsibly can be used to prevent and treat ailments that do not need medical consultation. This reduces pressure on

International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 4 July-Aug 2021, pp: 1419-1426 www.ijprajournal.com ISSN: 2249-7781

medical services, when these 7are limited, especially for those populations living in rural or remote areas where access to medical services may be difficult. Patients are able to control their own conditions to a greater extent. The factors contributed to prescription drugs being deregulated to over-the- counter (OTC) sale and new drugs with specific pharmacological action have been successfully reclassified from prescription to non-prescription status in many countries.

Over the Counter (OTC) and Prescription Drugs

Over-the-counter (OTC) refers to the process of how securities are traded via a broker-dealer network as opposed to on a centralized exchange. Over-the-counter trading can involve equities, debt instruments, and derivatives, which are financial contracts that derive their value from an underlying asset such as a commodity.In some cases, securities might not meet the requirements to have a listing on a standard market exchange such as the New York Stock Exchange (NYSE). Instead, these securities can be traded over-the-counter.However, over-the-counter trading can include equities that are listed on exchanges and stocks that are not listed. Stocks that are not listed on an exchange, and trade via OTC, are typically called over-the-counter equity securities, or OTC equities.

Prescription OTC Drugs

• Prescription drugs are available only by recommendation of an authorized health professional, such as a physician.
• Nonprescription (over-the-counter, or OTC) drugs are available on request and do not require approval by a health professional.
• Prescription and OTC drugs have been viewed differently by the public sine the classifications were established by the Durham-Humphrey Amendment of 1951.
• In general, the public views OTC drugs as minimally effective and safe and prescription drugs as more potent and frequently dangerous
• However, these distinctions are not always accurate

OTC Drugs Interesting Facts

• Each year the U.S. spends over 14 billion on OTC drugs
• More than 300,000 different OTC products are available on the market
• OTC expenditures comprise 60 of the annual drug purchase in the U.S.
• An estimated 3 out of 4 people routinely self-medicate with these drug productsAbuse of OTC products
• OTC products generally have a greater margin of safety than their prescription counterparts, but issues of abuse need to be considered.
• Physical dependence
• Psychological dependence
• Nonprescription products that can be severely habit-forming decongestants, laxatives, antihistamines, sleep aids, antacids and ephedrine.
• The active ingredients in OTC drugs have been classified and placed in category I (considered safe and effective)
• However, as recently as 1992, the FDA has banned over 400 ingredients from 7 categories of OTC products.

OTC drugs and self-care

• More than one-third of the time people treat their routine health problems with OTC medications to receive symptomatic relief from their ailments.
• If done correctly, self-care with OTC medications can provide significant relief from minor, self-limiting health problems at minimal cost.

OTC Labels

• Required label information includes
• Approved uses of the product
• Detailed instructions on safe and effective use
• Cautions or warnings to those at greatest risk when taking the medicationLabel information controlled by the FDA

When to use How to use What to watch for Possible drug interactions When drug should no longer be used Product name Identity Active ingredients Quantty Manufacturer Rules for proper OTC drug use

• Always know what you are taking.
• Know the effects.
• Read and heed the warnings and cautions.
• Don’t use anything for more than 1 to 2 wks.
• Be particularly cautious if also taking prescription drugs.
• If you have questions, ask a pharmacist.
• If you dont need it, dont use it!

Types of OTC drugs

• Internal analgesics
• Analgesics
• Salicylates
• Therapeutic considerations
• Analgesic actions
• Anti-inflammatory effects
• Antipyretic effects

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• Side effects
• Cold, allergy and cough remedies
• Decongestants
• Antitussives
• Expectorants
• Vitamin C

• Sleep aids
• Melatonin
• Stimulants
• Look-alike and act-alike drugs

Generic and proprietary drugs

• Generic is the official, nonpatented, nonproprietary name of a drug. The term generic is used by the public to refer to the common name of a drug that is not subject to trademark rights.
• Proprietary a brand or trademark name that is registered with the U.S. Patent Office. Proprietary denoted medications marketed under specific brand names, i.e., Valium.

Common categories of prescription drugs

• Analgesics
• Low-potency (Darvon)
• Moderate potency (Percodan)
• High-potency (Demerol)
• Antibiotics
• Antibacterials

Advantages of OTC products:

• benefits outweigh risk
•low misuse & abuse potential
• consumers are able to
Self diagnose
Self treat
Self manage
• adequately labeled
• health practitioners are not needed

Disadvantages of OTC Drugs

•patientmay choose wrong drug .
•patient may not know reactions or interactions .
•Ineffective treatment may result in progression of disease.

OVER THE COUNTER DRUGS EFFECT ON CHILDRENS:

Use of non-prescription drugs (NPDs), including over-the-counter drugs (OTCDs) and complementary alternative medicines (CAMs), is widespread all over the world as a first course of action for a range of childhood complaints. These include mild and moderate conditions, pain and fever and behavioural problems, such as irritability or sleeplessness.

OTCDs are defined as safe and effective for use by the general public without a doctor's prescription whereas CAMs are a group of diverse medical and health care practices that are not considered part of conventional medicine CAMs are usually regarded safer than conventional medicines. Parents may give CAMs to their child

after having tried conventional medicines without success or in association with conventional medicines. The reason for CAMs use may also be the opportunity to have more options in the health care of children and to increase the likelihood that something would be helpful for the child.

The use of NPDsis not free ofrisks, even if adverse effects ofCAMs have been found to be minor and self-limiting. Inappropriate treatment of illness and symptoms can lead to unnecessary medication use and possible adverse effects, if the parents' personal experience is not associated with the right information given by the physician.

DRUG INTERACTION WITH OVER-THE-COUNTER DRUGS:

The use and availability of over-the-counter (OTC) medication is increasing. Although regulatory agencies take care to assure than non-prescription medications are safe and effective, these drugs still have the potential to have clinically significant interactions with prescription medicines. The major classes of OTC medication to be considered in this light include antacids, histamine H2 receptor antagonists, NSAIDs, cough and cold preparations and the antiasthma products.

Healthcare providers and patients/consumers should be educated regarding possible drug interactions, patient drug regimens should be simplified where possible, and all therapeutic failures and adverse reactions should be investigated with regard to the potential contribution of OTC drug products. Regulatory agencies and pharmaceutical manufacturers should ensure that non-prescription drug labelling is complete and intelligible to meet these objectives. Consideration should be given to improving the post marketing surveillance of OTC medications.

■ **Factors Influencing Self-Medication Decisions**

Economic pressures are a major determinant of individuals' decisions to take OTC medications. This is undoubtedly related to the observations that the average American consumer

International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 4 July-Aug 2021, pp: 1419-1426 www.ijprajournal.com ISSN: 2249-7781

experiences a self-treatable health problem every 3 days. It is

no surprise that such a patient would prefer the availability of a relatively inexpensive OTC remedy to the cost in time and money of seeking medical consultation. By 1996,40% of all drug purchases in the US are expected to be OTC drugs. In addition to individual economic and convenience incentives, there are also economic benefits tosociety that must be considered. Lost revenues due to work absence alone would total over $US9 billion if OTC drugs were not available in the US.

The gross US savings (cost of work time lost, visits to doctors, prescription drug costs, etc.) due to OTC drug availability is estimated to increase to $US73 billion by the tum of the century. Similar observations are noted in other countries such as Germany in which the health costs would increase by $US 1.2 billion if OTC drugs were not available. The effect of advertising and direct-to-consumer promotion on self- medication use should be considered. In many countries such as the US, OTC drugs have regulatory advantages over prescription products in the use of direct-to-consumer mass media advertising vehicles. Pharmaceutical marketing budgets are large for both prescription and OTC drugs and are, undoubtedly, successful in creating a demand for these drugs and may foster a cavalier attitude regarding their safety on the part of the consumer.

1. Populations at Risk for Prescription/Over-the-Counter (OTC)
Drug Interactions

Certain segments of the population are at heightened risk for significant drug interactions between prescription and OTC drug products. For economic, social and physiological reasons, the elderly is at particular risk. l8] In a survey of an independently living geriatric population in the US, prescription drugs were taken by 75% of the study population, while 82% used a nonprescription drug regularly.

Patients over 65 years of age take more prescription medications than the generalpopulation and the elderly also use a larger number of OTC drugs including analgesics, nutritional supplements and cathartics than the general population. The anticipatedincrease in numbers of people over 65 years of age will magnify the importance of thisissue. It is estimated that by the year 2030, 64 million Americans will be over 65 yearsold. The patterns are similar for other developed nations. In England, 15.3% of the population will be older than 65 years of age by the tum of the century.Similarly, the paediatric population may be at increased risk forOTC/prescription drug interactions as a result of unsuspected or undocumented non-prescription drug utilization. Up to 28% of British children use an OTC drug product over a 2-week period and as many as 66% use a non-prescription drug over a 4-week interval. A more recent publication indicates that greater than half of all mothers had given their pre-school children an OTC medication, predominantlyparacetamol (acetaminophen) or cough/cold medications, in the previous 30 days.Organ transplant recipients are particularly vulnerable to OTC/prescription druginteractions. These patients are frequently treated with prescription drugs with narrow therapeutic indices and have varying degrees of organ dysfunction HIV-infected patients use a large number of prescription and OTC drugs and may be more prone to adverse drug interactions. In an HIV trial, 14% of patients with AIDS used more than 10 concomitant drugs Greenblatt and colleagues estimate that of all participants in HIV treatment trials, 96% use a mean of 4.85 other prescription drugs and 67% use a mean of 1.98 concomitant OTC products.

2. Clinically Significant Prescription/OTC Drug Interactions

In the section below, we have attempted to provide discussions, by selected OTC class, of clinically important OTC/prescription drug interactions. Since the availability of some OTC drugs varies by country, some interactions may not be applicable to all readers.

1. Antacids
3.1. 1 Antacids and Quinolone Antibiotics

The concomitant administration of aluminum or magnesium hydroxide with ciprofloxacin results in dramatic reductions in ciprofloxacin bioavailability while the absorption of other quinolones (fleroxacin, enoxacin, lomefloxacin and ofloxacin) is also affected, alterations in ciprofloxacin absorption are the most striking. Determined ciprofloxacin bioavailability was not significantly affected when administered either 2 hours before or 6 hours after the antacid.

3. 1.2 Antacids and NSAID

An NSAID class/antacid interaction is not clearly characterized in the literature.However, alterations in relative bioavaibility when given

International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 4 July-Aug 2021, pp: 1419-1426 www.ijprajournal.com ISSN: 2249-7781

concomitantly with antacids versus fasting have been reported for indomethacin fen Dosal, naproxen and diflunisal in patients with sub-therapeutic responses to these medications, an antacid interaction should be suspected.

3. 1.3 Antacids and Beta-Lactam Antibiotics

Some oral antibiotics are esterified prodrugs requiring acid- dependent de-esterification in the gut. The bioavailability of the prodrugs cefpodoximeproxetil,bacampicillin (as ampicillin) and cefuroxime axetil are significantly decreased when administered with antacids.

3. 1.4 Antacids and Other Miscellaneous Drugs

The bioavailability of tetracycline is reduced by 90% versus fasting when given concomitantly with magnesium or aluminum hydroxide ge1 Absorption of ketoconazole is pH-dependent and patients receiving this antifungal should receive antacids at least 2 hours after administration of ketoconazole. Aluminum or magnesium hydroxide antacid administration decreased bioavailability of single doses of captopril given to volunteers by approximately 50% relative to fasting; however, no pharmacodynamic change in blood pressure was detected. There has been a large number of interactions involving antacids reported in the literature recently. However, the clinical relevance of these interactionsis not currently clear.

3.2 Histamine H2 Receptor Antagonists

Cimetidine binds directly to several cytochrome P450 isoenzymes, inhibiting the oxidation of other drugs depending on these systems for metabolism. Ranitidine binds with a lesser affinity, while no binding was observed with either nizatidine or famotidine. Thus, based on in vitro studies, significant interactions would be expected with cimetidine, occasional problems with ranitidine and few if any interactions with famotidine or nizatidine. Significant cimetidine interactions [with benzodiazepines, warfarin, theophylline, antiepileptics, lidocaine (lignocaine) and beta-blockers] are detailed in Somogyi and Muirhead's 1987 review of cimetidine interactions. To date, no significant nizatidine or famotidine interactions have been reported.

3.2.2 H2-Antagonists and Warfarin

Both cimetidine and, to a lesser extent, ranitidine can decrease the clearance of orally administered warfarin, with resulting prolongations of prothrombin time.

3.2.3 H2-Antagonists and Antiepileptic's

Somogyi and Muirhead reviewed several studies indicating a significant cimetidine/phenytoin interaction and concluded extreme caution should be exercised when phenytoin is co-administered with cimetidine. Shaw et a1 reported decreased apparent oral clearance of clomethiazole (chlormethiazole; a sedative/anticonvulsant) and increased somnolence when co-administered with cimetidine. While cimetidine has been implicated in the reduction of carbamazepine epoxidation, the literature does not suggest that this interaction is clinically important.

3.2.4 H2-Antagonists and Theophylline

Many studies have reported clinically significant increases in theophylline concentrations, accompanied by signs of toxicity, in patients receiving cimetidine While Powell et al concluded that at normal therapeutic dosages (l50mg twice daily),ranitidine did not significantly alter theophylline clearance, Fernandez and Melewicz reported elevations of serum theophylline concentrations with toxic adverse effects following introduction of ranitidine therapy.

3.2.6 H2-Antagonists and Beta-Blockers

The addition of cimetidine usually decreases the clearance of P- blockers that undergo oxidative metabolism. Feely et al reported that cimetidine significantly reduces the clearance of propranolol without affecting its bioavailability. Cimetidine increased the bioavailability of oral labetalol by 14%; this was accompanied by a more rapid pulse rate and a greater decrease in blood pressure. Reports on the effect of cimetidine on metoprolol yield conflicting information. A multiple-dose study showed a significant increase in AVC with no change in clearance, while a single-dose (metoprolol) study showed no effect. Kelly et al completed 2 studies showing significant serum metoprolol concentration elevations following ranitidine administration versus fasting, without a significant pharmacodynamics effect.

3.3 NSAIDs

The widely used NSAIDs aspirin (acetylsalicylic acid), ibuprofen and naproxen are available as OTC drugs in most countries. While clinically significant interactions with NSAIDs are uncommon, potential

International Journal of Pharmaceutical Research and Applications
Volume 6, Issue 4 July-Aug 2021, pp: 1419-1426 www.ijprajournal.com ISSN: 2249-7781

interactions are present in half of all patients being treated for symptoms of arthritis.

3.3. 1 NSAIDs and Oral Anticoagulants

O'Reilly reported that high dosages of aspirin augmented warfarin- induced hypoprothrombinaemia and hemorrhagic signs. Extreme caution should be exercised when administering any NSAID or aspirin-containing product to patients who are anticoagulated.

3.3.2 NSAIDs and Oral Antihyperglycemic Agents

High doses of salicylates have been implicated in significant chlorpropamide, tolazamide and tolbutamide interactions. In vitro studies have shown that salicylates displace tolbutamide and chlorpropamide from plasma protein binding sites and also possessintrinsichypoglycemic activity. Therefore, alternative OTC NSAIDs may be preferable for patients receiving oral antihyperglycemic therapy

.3.3.3 NSAIDs and Ant

Aspirin has been shown to displace phenytoin from plasma proteins, increasing the free fraction and enhancing the clearance of unbound drug. Since folic acid is required for phenytoin clearance and may be depleted by increased phenytoin turnover, the resultant folic acid deficit may result in phenytoin intoxication. The aspirin valproic acid (sodium valproate) interaction is more complicated in that it may involve a similar displacement component as well as a (high dose) aspirin-induced inhibition of beta-oxidation, the main metabolic pathway for valproic acid) Caution should be exercised when patients require concomitant aspirin and valproic acid therapy.

3.3.4 NSAIDs and Digoxin

NSAIDs reduce the clearance of renally excreted cardiac glycosides. The very young, elderly or intravascularly depleted individuals are most susceptible to this interaction. Renal function and digoxin concentrations should be monitored closely in this group of pa

3.3.5 NSAIDs and Lithium

Ibuprofen and naproxen have been shown to significantly increase serum lithium concentrations in patients with normal renal function. There is no convincing evidence to suggest that aspirin significantly affects lithium concentrations.

3.3.6 NSAIDs and Methotrexate

The risk of a serious NSAID/methotrexate interaction is low in patients with normal renal function receiving low dosage methotrexate therapy (< 20 mg/week). However, patients with renal impairment may be at increased risk of methotrexate toxicity. In patients receiving moderate to high dose methotrexate therapy, caution must be exercised when concurrent NSAID therapy is instituted, to avoid serious renal toxicity.

3.3.7 NSAIDs and Cyclosporin

Altman et al demonstrated that co-administration of NSAIDs and cyclosporine caused in renal function. When these drugs are used together, renal function and cyclosporin concentrations should be carefully monitored.

3.3.8 NSAIDs and Antihypertensive Agents

NSAIDs have been shown to decrease the hypotensive response to thiazides, beta-blockers and vasodilators. Although this effect was initially thought to be specific to certain classes of NSAIDs, recent meta- analyses and case-control studies indicate that it is probably related to the pharmacological properties

3.3.9 NSAIDs and Other Miscellaneous Agents

The reduction in renal function associated with NSAID use should be considered when patients are being treated with renally excreted drugs such as arninoglycosides. Aspirin and naproxen have been shown to inhibit zidovudine glucuronidation by 10 to 30%.

3.4 Cough, Cold and Allergy Preparations

3.4. 1 Antihistamines

First generation antihistamines have secondary anticholinergic and antimuscarinic pharmacological properties that may potentiate the CNS depressant effects of benzodiazepines, barbiturates, opioids and phenothiazines, resulting in increased somnolence, impairment of cognitive function, dry mouth, blurred vision and urinary retention. Terfenadine and as temizole are generally devoid of sedative properties at clinically recommended doses and are available OTC in many countries.

3.4.2 Decongestants

Phenylpropanolamine and pseudoephedrine are sympathomimetic vasoconstrictors that are available as oral decongestants and can antagonize the hypotensive

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Volume 6, Issue 4 July-Aug 2021, pp: 1419-1426 www.ijprajournal.com ISSN: 2249-7781

effects of drugs used to lower blood pressure. Concomitant administration of monoamine oxidase inhibitors (MAOIs) and these OTC decongestants may result in hypertensive crises and cardiac arrhythmias.

3.5 Antiasthma Products

3.5. 1 Ephedrine

Since ephedrine causes the release of noradrenaline, co- administration of an MAOI could result in potentially fatal hypertension.

3.5.2 Theophylline

The clearance of theophylline has been shown to be significantly altered by many different drugs. Major inducers of theophylline metabolism include phenobarbital (phenobarbitone), carbamazepine, phenytoin and rifampicin (rifampin). Macrolide and qui no lone antibiotics, as well as cimetidine, have been shown to reduce the rate of theophylline metabolism. Careful therapeutic drug monitoring of theophylline is recommended when given concomitantly with an interacting agent.

AIM:

To avoid the complications of over the counters drug by giving awareness to the common people and decrease the drug interactions by recruiting professional pharmacist and people should have prescription for medication along with the date.

The specific objectives of the study:

People should have minimum knowledge about drug interactions

• The government should give awareness through media

• The government should provide guidelines to the retail pharmacy for OTC drugs.

II. DISCUSSION

This review of the literature has revealed a number of themes and data to inform understanding of OTC medicine abuse, However, what is perhaps most apparent is the extent of the omissions in the extant literature, particularly as they relate to the lack of:• qualitative methods that may be appropriate for exploring individual perspectives;

• reliable quantitative data in some countries;

• fully evaluated or implemented interventions;

• data relating to Internet supplies; and consensus over definitional terms.

This review confirms that there is a problem in a number of countries but concerns about what is being investigated – whether this is misuse, abuse, dependency, addiction or pseudo-addiction – coupled with a lack of systematic data on the scale of the problem make appropriate and proportionate policy-based interventions difficult to consider. There exists a tension between making OTC medicines available to individuals to increase their access to medicines and enabling them to self-manage conditions and accepting that there is some degree of risk of such products being misused or abused, with potentially serious consequences for some. Raising awareness of potential problems of OTC medicines, as the recent response in the United Kingdom has illustrated in terms of making purchasers aware of the possibility of addiction, would appear a prudent response. But whilst this may arguably warn those using products for the first time, for those with an existing problem, more support may be needed in the clinical pathway.

III. CLASSIFICATION:

The Role of Good Classification Practices in Promoting Medication Safety and Accessibility in Europe" brought togethe r national and European health authorities, healthcare professionals, patients' organisations, the pharmaceutical industry and pharmaceutical wholesalers to explain the mandate and work of the Committee of Experts on the Classification of Medicines as regards their Supply (CD-P-PH/PHO), to collect feedback from different stakeholders on the main themes of the event, and progress towards harmonisation of good classification practices for OTC medicines, thus promoting safe and accessible medicines for patients in Europe.

The following is a summary of the main conclusions and recommendations grouped according to the workshop's three themes. Patients' Awareness and Education with respect to Safe and Appropriate Use of Medicines, with Special Attention to OTC Medicines - Importance of patient-centred healthcare: by definition, healthcare should be focused on patients. To ensure that healthcare remains true to this central purpose, proactive collaboration among different stakeholders (e.g. national and European health authorities, pharmaceutical industry, and healthcare professionals) is strongly encouraged. In particular, a concerted effort should be made to deliver clear, easy-to-understand, reliable and neutral information on both prescription and non-prescription medicines. This will enable patients to take responsible decisions and use their treatments safely and effectively.

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IV. CONCLUSION

This review of the literature relating to OTC medicine abuse has revealed that There is a recognised problem internationally involving a range of medicine and potential Harms , these represent urgent areas where research is needed to explore the extent of the problem and to provide insight into those affected coupled with providing clarification of the Type of problem being investigated. Such research is needed to inform policy regulation and The preparedness of a range of health care professionals to avoid harm to those who purchase OTC medicines that may be liable to abuse. Overall we can conclude from different cases studies both as well as prescription drugs have Equal importance both having advantages and disadvantages also though safety margin of Prescribed drugs is more , OTC drugs can not be labelled unsafe due to their large occupancy In the OTC drugs as comparative to prescribed drugs but prescribed drugs are under physician Supervision hence there are low chances of toxicities.

Advantages of OTC drugs : low misuse and abuse potential , consumers are able to : self Diagnose and self treat and self manage , and health practitioners are not needed.

Disadvantages of OTC drugs : the patient may choose wrong drug , patient may not know Reaction or interactions , ineffective treatment may result in progression of disease.

Pharmacy students should give awareness to the surrounding people to avoid Complications .

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