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A REVIEW ARTICLE ON OVER-THE-COUNTER DRUGS

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Abstract:

Over-the-counter (OTC) drug is a medicine that is available without a prescription, and hence also referred to as "non-prescription drug." The sale of OTC medicines from pharmacies can help individual's self-manage symptoms. However, some OTC medicines may be abused, withaddiction and harms being increasingly recognized and found to be more common in more people.

Shall mostly refer to medicines that are only available in pharmacies, rather than those on the General Sales List, which are available through supermarkets and other outlets without the supervision of a pharmacist. I shall also assume that pharmacists are alive to the problems of self-medication by patients and will take steps to advise them about seeking medical advice when appropriate. This is not true in all countries, and I shall therefore mostly restrict my comments to the UK, where it is. Self-care and self-medication are common practices in any health care system.

Abuse is characterized as over-consumption beyond the approved medical practice or medical norms when the hazards and unfavourable consequences outweigh the advantages.These include self-medicating at higher quantities and for longer periods of time than recommended. Improved knowledge, understanding about self-medication result in rationale self-medication procedure includes the usage of Over-the-counter or non-prescription drugs which are obtained by individuals without a prescription from a physician for the treatment ofcommon ailments. Lower costs, convenience, availability, and the ability to control one's own illness are the potential benefits of over-the-counter- drugs. The risk of drug misuse, dependence, and adverse drug events is increased when the drugs are used inappropriately. Misuse and use. There is an urgent need to implement legislation to promote judicious and rational use of over-the-counter drugs The sale of over-the-counter (OTC) medicines from pharmacies can help individuals self-manage symptoms.

OTC medicine abuse was identified in many countries and although implicated products varied,five key groups emerged: codeine-based (especially compound analgesic) medicines, cough products (particularly dextromethorphan), sedative antihistamines, decongestants and laxatives.. Associated harms included direct physiological or psychological harm (e.g. opiate addiction), harm from another ingredient (e.g. ibuprofen-related gastric bleeding) and associated social and economic problems. Strategies and interventions included limitingsupplies, raising public and professional awareness and using existing services and Internet The public generally believes OTC medicines to be helpful for treating minor ailments.

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INTRODUCTION:

The trend of 'Over-the-Counter (OTC) Medicines' use has grown steadily in the last few years. Various reasons such as easy availability, affordability, and increased awareness among patients are responsible for this trend. OTC medicines or non-prescription medicines are termsused interchangeably to refer to medicines that can be bought without a prescription. Many countries recognize OTC medicines as a separate category of drugs and have established

regulations for their use. In India, till date there are no guidelines for licensing of OTC medicines. There is no separate category allotted for OTC medicines in India and the drugs which do not come under the prescription medicines schedule are generally sold as over-the- counter medicines.

Patients often approach a pharmacist instead of visiting a doctor for minor ailments such as cough, cold, allergies, pain, fever, acidity, diarrhoea, and skin-related conditions. Purchase of specific medicines over the counter is legally recognized in most countries. 'Over-the-Counter (OTC) Medicines' means drugs which are legally allowed to be sold by pharmacists without need for a prescription. The term does not have a legal definition in India. Technically, drugs are OTC unless they are specifically stated as prescription only drugs. OTC drugs allow faster and cheaper access to healthcare; however, their misuse and adverse health effects cause concerns. This article describes concept of OTC medicines and practices in India against the background of globally prevalent regulations and practices. A recognized category of OTC medicines by law, patient awareness programs, and support of pharmacists and pharmaceutical companies are required to optimize the use of OTC medicines in India. This review article makes an attempt to throw light on the regulatory and clinical scenario of "OTC medicines" inIndia against the globally prevalent practices.

"OTC," has "self-medication," "prescription," and "without prescription available drugs. Among these, the articles fulfilling the following criteria were chosen: Articles with the above- mentioned search terms in their title, studies in English language published in peer-reviewed journals, and studies that mentioned about the regulatory and/or clinical scenario pertaining toOTC medicines. There were no restrictions on the date of publication. The search was conducted by 2 independent authors; both of them screened the articles independently for relevance and completeness. Articles containing overlapping or duplicate information were excluded. Only a limited number of articles fulfilling the above stated criteria were finally selected. Of these, 46 were full text articles, 1 was an editorial, and 2 were conference proceedings. The information available from electronic media (newspapers and websites) has been quoted occasionally.

Use of over-the-counter medicines (OTC): Scenario across different a report on global OTC markets states that countries such as the United States, Japan, Germany, and the United Kingdom contribute maximally to the worldwide OTC sales. The USA, UK, Australia, and Japan have formulated guidelines regarding classification, regulation, and uses of OTC. Distinction between OTC and prescription medicines may not always be obvious. For instance, in New Zealand, low-dose ibuprofen (200 mg) is OTC to treat minor pains such as headache, while high-dose ibuprofen (400, 600, and 800 mg) is a prescription-medicine used for the treatment of severe pain associated with arthritis. OTC medicines can be classified into two categories: First category of OTC medicines are the ones which have been under the categoryof non-prescription medicines since the time they were introduced. The second category of OTC medicines are those that had been prescription medicines initially but were later shifted to the OTC category. According to WHO, for a product to be an OTC medicine, it should be marketed on prescription for at least 5 years. Before accepting switch of a given drug into OTCcategory, it is important to ensure that the drug did not cause serious adverse drug reactions with increasing frequency during the marketing period till then.

Over-the-counter (OTC) drug is a medicine that is available without a prescription, and hence also referred to as "non-prescription drug." The class of OTC drugs includes vitamins, tonics, iron preparations, analgesics, nonsteroidal anti-inflammatory drugs (NSAIDs), cough mixtures, skin care products, sore throat products, antipyretics, and laxatives. In India, the poor socio-economic status and unaffordable fees of doctors make the people relay on the self-medication advised by family members, friends, and pharmacist. As there is no regulation for OTC drugs in India; some studies showed that around 76% populations are regularly taking medication without any prescription. Reasons for self-medication could be modern lifestyle, busy working schedule and lack of time to seek doctor appointment and waiting for a longer period for consultation, because of these reasons patients go for alternative advice for illness from friends and family members, following blindly their old prescription for

similar symptoms. Other reasons could be milder illness and long distance of medical pharmacy shops, unaffordable fees of doctors and too much information getting from internet and magazines make people over confident in treating their own illness. The available medicines are restrictive compared to prescribed ones and there often limitation to indications and doses. However, deregulation is increasing from prescribed medicines to the OTC drugs through internet and online pharmacies.

HISTORICAL BACKGROUND:

In the olden days before the Food and Drug Administration (FDA) was founded, most drugs were available without a prescription, just about anything was put in a bottle and sold as a medicine. Narcotic Drugs and Psychotropic substances like Alcohol, Cocaine, Marijuana, and Opium were included in some OTC products without notifying the users. The Food, Drugs, and Cosmetic Act was framed and implemented in 1938 which authorized the FDA to issue clear guidelines to which drugs could be sold by prescription only and which could be sold as OTC.An amendment to the FD&C Act was brought into action in 1951 to clarify the difference between OTC and prescription drugs and to deal with issues of drug safety. Prescription drugswere defined as compounds that could be habit-forming, toxic, or unsafe for use except under a doctor's supervision. Whatever else could be sold as OTC.9 An additional amendment to the FD&C act was made in 1962 where medications were expected to be both effective and safe to be administered as OTC. Notwithstanding, deciding viability and well-being was troublesome in those days. What is powerful for one individual may not be so for another and any medication might cause undesirable adverse effects.

CURRENT INDIAN REGULATIONS: FOR OTC Government and non-government public health organizations have increasingly raised concerns regarding the misuse, abuse, and dependence on OTC medication in India.10 Easy access with little to no restriction on quantity to a wide range of OTC medicines is the main factor responsible for irrational use resulting in threatening health complications (antimicrobial resistance, increased mortality and morbidityrate) and economic damage. Failures in the pharmaceutical regulatory environment in India combined with poor community literacy about medication safety and usage, potentiates misuse and overuse of medications leading to dependence. Owing to insufficient guidelines and knowledge of a few drugs that are not categorized under any schedule has risen confusion and uncertainty in pharmacists regarding whether to dispense the medicine as OTC or not.

However, few articles and reports suggest that the Government is taking into consideration and is likely to identify and prepare a list of OTC drugs in due course. This development comes in certain recommendations made by the Drugs Consultative Committee (DCC). The DCC recommended that a suitable amendment should be made in Schedule K of the D&C Rules to incorporate necessary provisions for OTC drugs for providing exemptions from requirements of prescription and/ or sale license, subject to appropriate conditions during its 57th meeting,held on August 20, 2019. The sale of over-the-counter (OTC) medicines from pharmacies can help individuals self-manage symptoms. However, some OTC medicines may be abused, with addiction and harms being increasingly recognised. This review describes the current knowledge and understanding of OTC medicine abuse.
Findings:

OTC medicine abuse was identified in many countries and although implicated products varied, five key groups emerged: codeine-based (especially compound analgesic) medicines, cough products (particularly dextromethorphan), sedative antihistamines, decongestants and laxatives. No clear patterns relating to those affected or their experiences were identified andthey may represent a hard-to-reach group, which coupled with heterogeneous data, makes estimating the scale of abuse problematic. Associated harms included direct physiological or psychological harm (e.g. opiate addiction), harm from another ingredient (e.g. ibuprofen- related gastric bleeding) and associated social and economic problems. Strategies and interventions included limiting supplies, raising public and professional awareness and using existing services and Internet support groups, although associated evaluations were lacking. Terminological variations were identified.

OTC medicine abuse is a recognised problem internationally but is currently incompletely understood. Research is needed to quantify scale of abuse, evaluate interventions and capture individual experiences, to inform policy, regulation and interventions.

OBJECTIVES:

1. To know the awareness levels of consumers about OTC drugs.

2. To know what kind of information they seek about the OTC drugs
3. To know whether they read instructions on the OTC drugs.
4. To study the influence of demographical factors on awareness of OTC drugs

OTC DRUGS

Definition:

"OTC medication are those medication that can be obtained Over the counter or from the chemist bench without the Prescription of a RPM and consultant with a physician.it can be suggested that those having little significant pharmacological activity and therefore the physician need not to be very much concerned about these use by the patient themselves.''

- It is also called prescription de-controlled drugs.
- These drugs are the non-prescription or over -the -counter drugs.
- These have little significant pharmacological activity and therefore the physicianneed not to be very much concerned about their use by the patient themselves.
- It is used primarily for symptomatic relief and as a substitute for prescription drugs.

OTC MEDICATION HISTORY:

- In 1860s the preparation of remedies at home was replaced by purchasing of patientmedicines.
- By 1905 the market of the patent drug was at its peak
- 1920 due to intense economic and political struggle changed preference care, resulted in demand and use of patient medicines.

OTC MEDICATION IN INDIA:

- In India, the medicine are listed under different schedules in the drugs and cosmetics act and drugs and cosmetics rule. Drugs listed in schedule H H1, and X should carry a label stating that these drugs are to be sold by retail only on prescription of a registered medical practitioner.

- It has to be stressed that in India, the phrase ''OTC" has no legal recognition. Here the term OTC is used for the way drugs are used [self-medication] without prescription or allowed to be sold by pharmacist without the prescription of a registered medical practitioner] rather than being a recognised official category ofmedicines unlike other countries.
- Schedule K of the drug and cosmetics act and its rules includes household remedies paracetamol, liquid paraffin, eucalyptus oil, tincture iodine, and various formulations for the treatment of cough and cold and are the potential OTC drugs.

- Currently nondrug-licensed stores [e.g., non-pharmacists] can sell a few medicines classified as '' household remedies" in schedule K of the D and C rules in villages whose population is below 1000 subject to certain other conditions. Under the provision of the drugs and magic remedies [objectionable advertisements] act, 1954 and rules, 1955 the advertising and misleading promotion of some drugs/classes is *kept under control to avoid self-medication by people.*

- The medicines which do not fall under the category of schedule H, H17 & X can be given without prescription through pharmacist and drug stores in India. Moreover, it is a common observation that prescription drug are also sold without a prescription akin to over the counter medicines.

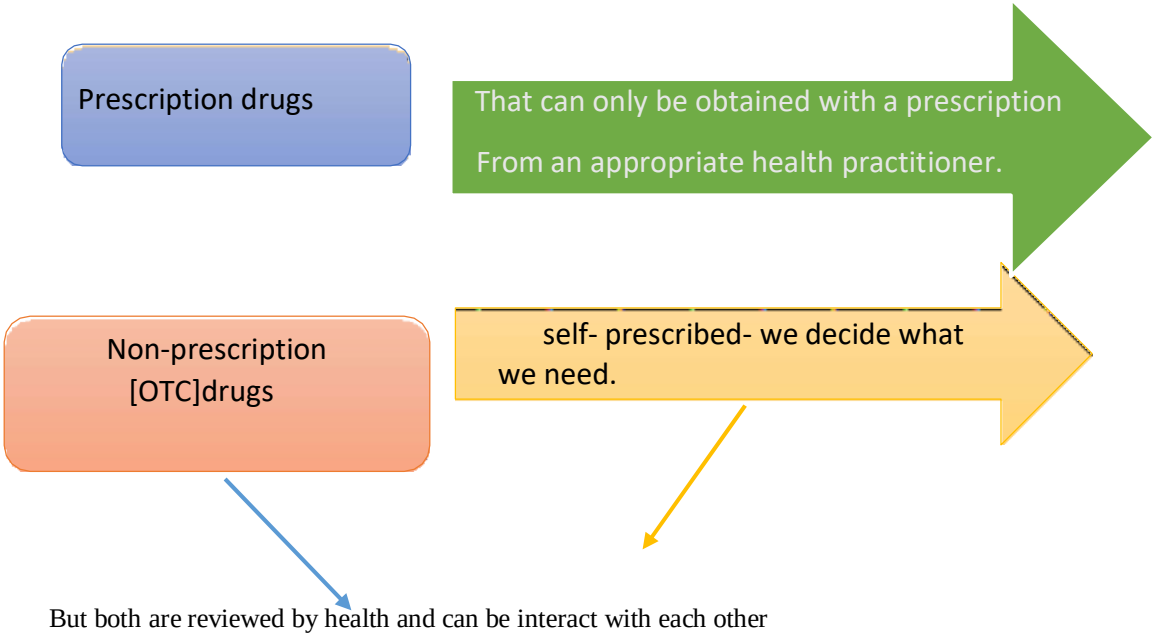
Medication are broadly classified in to two types:

1. Prescription controlled medication.
2. Prescription uncontrolled medication.

- Prescription controlled medication: this class involves the drugsand medicines which needed a signified prescription of eligible authority that is physician or a registered medical practitioner.
- Prescription uncontrolled medication: this class involves all the drugs and medicines which do not require a written prescription of a physician or a medical practitioner. Such medication can be directly purchases over the chemist, so the drugs are called as a over the counter drugs or non prescribed.
  - It's a non-prescription medicine.
  - In broader sense all non- prescription medicine including traditional herbal medicine or nutritional supplements [pharmaceutical care meaning].
  - A simply say to OTC.

"An OTC drug product is a product marketed for use by the consumer without the intervention of a health care professional.''

DIFFERENCE BETWEEN PRESCRIPTION & NON-PRESCRIPTION DRUGS



But both are reviewed by health and can be interact with each other

SIGNIFICANCE

- Comparatively cheaper
- Chemist himself may prescribe OTC
- Self-diagnose
- Self-treat
- Self-manage
- Indications for use
- Active ingredient
- Purpose
- Precautions on drug interaction

TYPES OF OTC MEDICATIONS

- DRUGS ANALGESICS
- ANTIBIOTICS
- COUGH SUPPRESSANTS
- ANTI ACNE DRUGS
- NSAIDS
- ANTISEPTICS
- DECONGESTANTS
- ANTACIDS
- ANTIFUNGALS
- ANTI HISTAMINE

SMOKING CESSATIONTOPICAL ANTIBIOTIC
Topical antibiotic is medicine applied to the skin to kills bacteria. They are used to treat or prevent infections that occur on minor cuts, scrapes, and burns due to presence of bacteria.

COUGH SUPPRESSANT
Cough suppressants are medicines that prevent or stop coughing. A cough suppressant is used for treating dry cough [antitussive].it helps to suppress the body's urge to cough.
Cough suppressant is different from cough expectorants. cough expectorants help in treating productive cough [cough that produce phlegm].

ANTI ACNE DRUGS
Anti-acne drugs are medicines are used in the treatment of various acne problems like pimples, whiteheads, and other serious forms of acne.

ANTISEPTICS MEDICINE
Antiseptic in the form of lotions, creams, ointments are medicines that slow or the growth of germs and help prevent infections in cuts, scrapes and burns.

ANTI-INFLAMMATORY DRUGS

Nonsteroidal anti-inflammatory drugs are medicines that are used to treat inflammation, mild to moderate pain, and fever. They are basically drugs with analgesic and antipyretics effects and with higher doses, they have anti-inflammatory effects.

ANALGESICS DRUGS

Analgesics are medicines that relieve pain.
DECONGESTANT

Decongestant are the drugs or medicine used to relieve nasal congestion, which in commonterms refers to stuffy noise.

ANTACIDS

Antacids are the medicine or drugs that neutralizes the stomach acids.

ANTIHISTAMINE
Anti-histamine are medicines that relieve or prevent the symptoms of allergy like Hay fever,itchy eyes, sneezing, runny nose and other kinds of allergy.

ANTI-FUNGAL DRUGS
Anti-fungal drugs are used to treat infections caused by a fungus.

SMOKING CESSATION DRUG
Smoking-cessation drugs are medicine that are used to help people stop smoking cigarettesor using other forms of tobacco.

RULES FOR THE PROPER USE OF OTC DRUGS

- 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 caution if also taking prescription drugs.
- If you have question, ask a pharmacist.
- If you don't need it, don't use it.

SPECIAL PATIENT GROUPS
Many patient groups may be particularly susceptible to adverse events that arecaused by OTC products. They include:

- Children
- Women who are pregnant or breast feeding
- Geriatric patient
- People taking prescription drugs and people having health problem

OTC MEDICATION ARE SAFE BUT NOT RISK-FREE

As with all medication, there can be risk with use. The risks of OTC use medication:

- Delay in seeking medical advice for a serious illness.
- Risk of drug -drug /herbal/dietary supplements interaction.
- Risk of adverse events.
- Potential for dependence, misuse abuse.

MISUSE AND ABUSE OF OTC DRUGS

- Physical dependence
- Psychological dependence

- Nonprescription products that can be severely habit-forming: decongestants, laxatives, antihistamine, sleep aids, antacids and ephedrine.
- In one survey it has been found that Only 16% read the entire products label.
- Abuse is most common in adolescents aged 10-17 years.
- Adolescents are 18% times more likely to dies from OYC overdose than froma illicit drug dose overdose.

Overdosing has occurred with non-prescription medicines, particularly thosethat contain paracetamol. Adverse reaction can also occur but rare.

Pharmacist should therefore ensure that advice and information are availableon the safe and effective use of medicine.

Products	Example
Solvents	methylated and surgical spirit
Propellants	pain relieving sprays
Chemicals	citric acid
Opioids	codeine, morphine
Laxative	senna

IN WHAT WAY THE OTC DRUGS CAN BE HARMFUL

- ✓ OTC drugs can change the effect of prescription medication.
- ✓ OTC drugs can mask symptoms of disease.
- ✓ OTC drugs can lead to overdose.
- ✓ If misused even common over-the-counter drugs, such as aspirin, vitamins, or cold remedies can be harmful.

OTC MEDICATION REASONS

→ Shortage of time and comfort

→ Cheaper in price

→ Availability

→Level of literacy and awareness

Self care

→Advertisement 1. SHORTAGE OF TIME:
Usually, people in cities and town due to their busy schedule don't get proper time for
visiting the physician for getting proper medications but OTC medication are available invery less time or less consuming time and easily.

2. CHEAPER IN PRICE:
In our country like India where more than 55% of total population is just near the poverty line people majority are weak to visit physician for small health problems and hence prefer non-prescribed drugs comparatively cheaper.

3. AVAILABILITY:

Most of the NPDS are easily available at all places. Due to the availabilities, there is easilypreferred by common people for daily health problems.

4. LEVEL OF LITERACY AND AWARENESSS:

Many of the people have either very low awareness due to which they don't prefer to visit aphysician.

5. SELF- CARE:

Now a days people with high literacy and awareness and preferred to use of OTCmedication. This is because self-care.

COUNSELLING FOR OTC PRODUCTS:

- ❖ patient's use of OTC products carries both benefits and risks.
- ❖ When pharmacist proactively counsel patients on OTC product selection and use, therisk virtually didapper.
- ❖ Pharmacists should have to counsel every Patient on the safe and effective use ofOTC product.
- ❖ The involvement of pharmacist in nonprescription medication counselling will increasing the public stability to understand the risk and benefits of OTC remedies.
- ❖ In order to counsel patients efficiently, pharmacists must be to communicate.
- ❖ The first step in achieving optimal communicate is setting the stage.

RATIONAL USE OTC DRUGS:

Definition

Use of an appropriate, efficacious, safe and cost-effective drug given for the right indication in the right dose and formulation, at right intervals and for theright duration of time.

ANALGESICS

Pain relief medicines [also known as ‘’analgesics” and ‘’ painkillers”] are regulated by the food and drug administration [FDA].

Some analgesics, including opioid analgesics, act on the body’s peripheral and central nervous system to block or decrease sensitivity to pain. Others act by inhibiting the formation of certain chemicals in the body.

These relieve the minor aches and pains associated with conditions such asheadaches, fever, cough, cold, flu, arthritis, toothaches, and menstrual cramps.

There are basically two types of OTC pain

→ acetaminophen

→ non- steroidal anti-inflammatory drugs [NSAIDS]

- Acetaminophen is an active ingredient found in more than 6oooTC and prescription Medicines, including pain relievers, cough suppressants, and cold medication.

- NSAIDs are common medication used to relieve fever and minor aches and pain. They include aspirin, naproxen, and ibuprofen, as well as many medicines taken for cold, sinus pressure, and allergies.

Use as Directed

Pain medication is safe and effective when used as directed. However, misuse of these products Can be extremely harmful and even deadly.

- Consumers who take pain relief medications must follow their health care professional’s instruction carefully. If a measuring tool is provided with yourmedicine, use it as directed.

- Do not change the dose of your pain relief medication without talking to your doctorfirst.

- Also, pain medication should never be shared with anyone else. Only your healthcare professional can decide if a prescription pain medication is safe for someone.

With acetaminophen:

→ Taking dose, a higher than recommended will not provide more relief and can bedangerous.

→ Too much can lead to liver damage and death.

→ risk for liver damage be increased in people who drink three or more alcoholic beverages a day while using acetaminophen containing medicines.

→ Be a caution when giving acetaminophen to children. Infant drop medication can be significantly stronger than regular children’s medication.

With NSAIDs:

→ Too much can cause stomach bleeding. This risk increases in people who are over 60 years of age, are taking.

Prescription blood thinners, are taking steroids, have a history of stomach bleeding or ulcers, and / or have other bleeding problem.

→ use of NSAIDs can also cause kidney damage. This risk may increase in people who are over 60 years of age, are taking a diuretic [a drug that increases the excretion of urine], have high blood pressure, heart disease, or pre-existing kidney disease.

With opioids:

- Use of opioids can lead to drowsiness. Do not drive or use any machinery that may injure you, especially when you first start the medication.

- The dose of an opioid pain medication that is safe for you could be high enough to cause an overdose and death in someone else, especially children.

Know the active ingredients

A specific area of concern with OTC pain medication is when products sold for differentuses have the same active ingredient. A cold and cough remedy may have the same ingredient as a headache remedy or a prescription pain reliever.

- To minimize the risks of an accidental overdose, consumers should avoid taking multiple medication with the same active ingredient at the same time.

- All OTC medicines must have all of their active ingredient listed on the package. For prescription

drugs, the active ingredient are listed on the container label.

Irrationality:

- Ineffective and unsafe drug treatment
- Worsening or prolonging of illness
- Adverse drug reaction
- Increases the cost to the patient
- Antibiotic resistance

Irrational prescribing Practices

- Prescribing drugs of no proven value
- Prescribing empirically
- Unnecessary prescribing for self-limiting conditions
- Overdosing and underdosing
- Prescribing costly drugs

Misuse of antibiotics

i. Common cold
ii. Upper respiratory infection
iii. Starting antibiotics without diagnosis
iv. Frequently changing antibiotics
v. Giving suboptimal dose
vi. Not completing the course of treatment

Rational use of antibiotics

- ✓ Use antibiotics only when indicated
- ✓ Before commencing antibiotic therapy, specimen for gram stain, culture, sensitivitytesting should be obtained
- ✓ Choice should be based on suspected causative organism, safety, previous clinicalresponse, cost, ease of use, potential for resistant organism
- ✓ Adequate dose and duration of treatment
- ✓ History of Allery or ADR
- ✓ Prophylactic use of antibiotics restricted
- ✓ Oral therapy preferred more than parenteral therapy
- ✓ Antimicrobial combination should only be used where indicated
- ✓ More effective and least toxic
- ✓ optical antibiotics restricted to few proven indication

Rational use of injections

a. Oral administration is not tolerated
b. Absorption problem
c. Drug of choice formulated as parenteral
d. High tissue concentration are needed
e. Urgent treatment required
f. Not comply with oral therapy

Factor contribute to incorrect use of medicines

- Lack of skills and knowledge
- Inappropriate unethical promotion of medicines by companies
- Profit from selling medicine
- Unrestricted availability of medicines
- Overworked health personnel
- Unaffordable medicines

Hazards of irrational use of drugs:

As we know medicines are essentially foreign substances to human body and if not used without most care, they can harm our normal physiological system. Hence, medicines need to be of good quality, safety, efficacy and besides this should be used rational.

1. Unsafe treatment.

Prolongation of illness. 3.Distress and harm to patient.

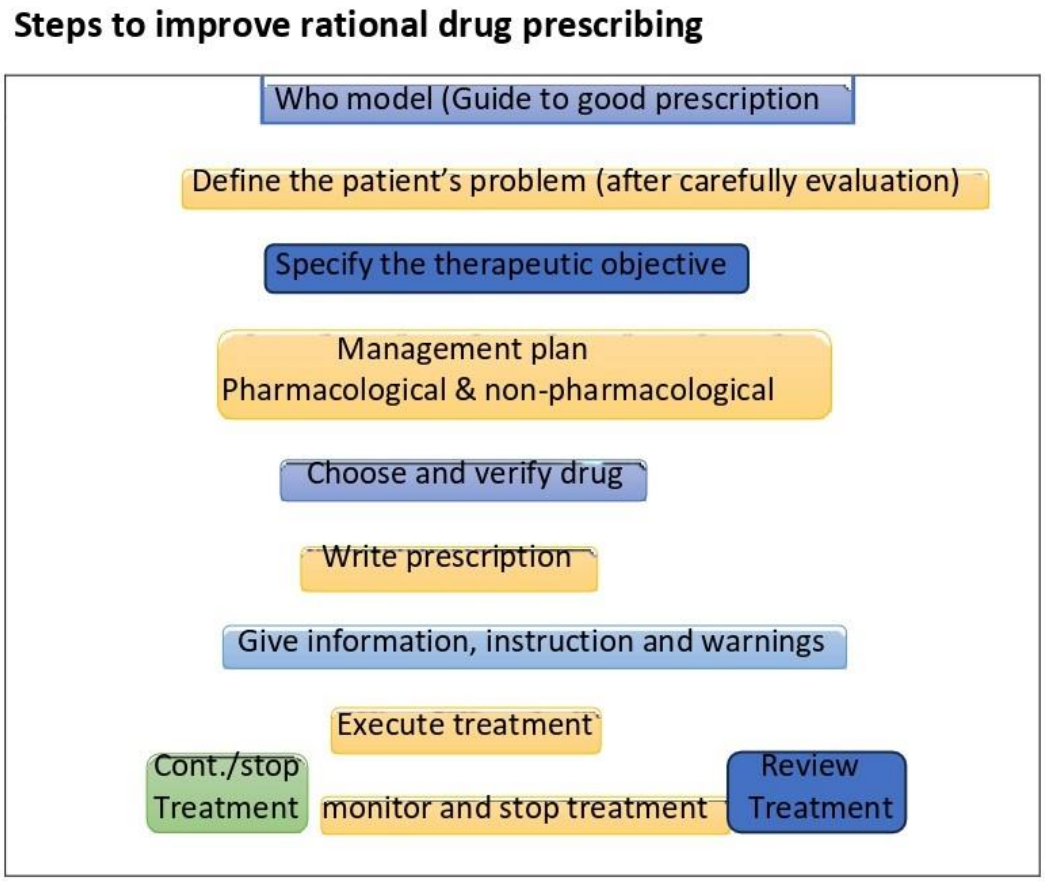
4. Increase in the cost of treatment.
5. Increased morbidity and mortality.
6. Adverse drug reactions.
7. Blood borne diseases like HIV.
8. Loss of patient confidence in health system.

Causes of irrational uses of drugs:

There are various causes of irrational uses of drugs.

1. Poly-Pharmacy.
2. Inappropriate antibiotics.
3. Overuse of drugs/misuse/under use.
4. Failure to prescribe in accordance with clinical guidelines.
5. Self-medication.
6. non-adherence of dosing regiments.
7. Lack of information.
8. Poor communication between health professionals and patients.
9. faulty and inadequate training and education of medical graduate.

Steps to improve rational drug prescribing



ROLE OF PHARMACISTS IN OTC MEDICATION DISPENSING:

The pharmacist plays a vital role in controlling the number of medications being dispenseOTC drugs. They can also counsel and advise the consumers regarding OTC medication

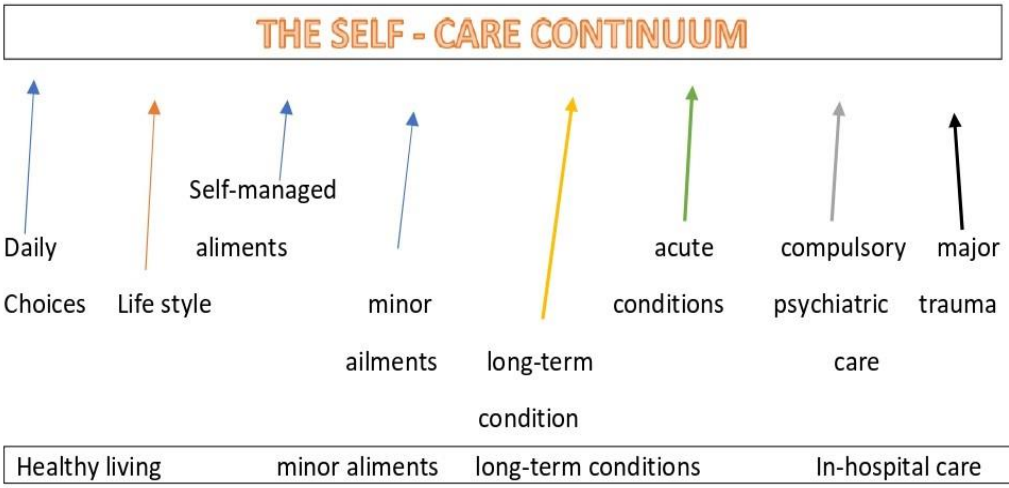
- Carefully read and follow all directions on the medicine bottle and box.
- Dispense the minimum effective dose.
- Call your doctor if you are think having a problem with you medicine.
- Do not give a medicine if patient have had an allergic reaction to it in the past.
- Inform patient to take the medicine exactly as directed.
- Pharmacist has to be carefully when dispensing more than one drug.

Self -medication:

- ✓ Fundamentally the concept "self -care" puts responsibility on individuals for theirown health and wellbeing.
- ✓ The world health organisation defines self-care as:
- ✓ "The ability of individuals, families and communities to promote health, prevent Disease, and maintain health and to cope with illness and disability with or withoutthe support of a health-care provider."

The self- care continuum

Pure self-care	**pure medical care**
Responsible	professional
Individual	responsibility



- A country with a huge population, like India, faces the challenge of an abysmally low doctor-to-patient ratio which creates a conducive atmosphere for preference towards OTC drugs to flourish. Some particular reasons for the same may be listed as below:

1. Having a previous prescription
2. Saving time
3. Family member's advice
4. High price of doctor's visit
5. Crowded medical centres
6. Lack of trust in doctors

Drug name	**Strengthened dosage form**
Acetaminophen	32mg tablet,160mg/5ml Suspension
Aspirin	81mg chewable tablet
Aspirin (enteric coated)	325mg tablet
Ibuprofen	200mg tablet,1oomg/5ml Suspension

Examples of some OTC drugs and their indications:

A-Systemically acting drugs: -

-Acyclovir	Antiviral.
–Brompheniramine	Antihistamine.
-Chlophendianol HCl	Antitussive.
-Chlorpheniramine	Antihistamine.
-Cholestyramine	Cholestrollowering drug.
-Cimetidine	Gastric acid reducer.

B-Topically acting drugs:

Butoconazol nitrate	Anticandidal.
Clotrimazole	Antifungal.
Cromolyn	Allergic rhinitis.
Ephedrine sulphate	Hemorrhoidal vasoconstrictor.
Epinephrine HCl	Hemorrhoidal vasoconstrictor.

There are two OTC medicines that are most commonly misused:

Dextromethorphan (DXM) is a cough suppressant found in many OTC cold medicines. The most common sources of abused DXM are "extra-strength" cough syrup, tablets and gel capsules. DXM may be swallowed in its original form or may be mixed with soda for flavour, called "rob -tripping" or "skittling. These medicines are often misused in combination with other drugs, such as alcohol and marijuana.

Loperamide is an anti-diarrheal that is available in tablet, capsule, or liquid form. When misusing loperamide, people swallow large quantities of the medicine. It is unclear howoften this drug is misused

These OTC medicines affect the brain

DXM is an opioid without effects on pain reduction and does not act on the opioid receptors. When taken in large doses, DXM causes a depressant effect and sometimes ahallucinogenic effect, similar to PCP and ketamine.

Loperamide is an opioid designed not to enter the brain. Other opioids, such as certain prescription pain relievers and heroin, bind to and activate opioid receptors in many areas of the brain, especially those involved in feelings of pain and pleasure. Opioid receptors are also located in the brain stem, which controls important processes, such as blood pressure, arousal, and breathing.

Opioid Withdrawal Symptoms:

- muscle and bone pain
- sleep problems
- diarrhoea and vomiting
- cold flashes with goose bumps
- uncontrollable leg movements
- severe cravings

The health effects of these OTC medicines

DXM:

Short-term effects of DXM misuse can range from mild stimulation to alcohol- or marijuana-like intoxication. At high doses, a person may have hallucinations or feelings of physical distortion, extreme panic, paranoia, anxiety, and aggression.

DXM misuse can include the following:

- hyperexcitability
- poor motor control
- lack of energy
- stomach pain
- vision changes
- slurred speech
- increased blood pressures
- sweating

Misuse of DXM products containing acetaminophen can cause liver damage.

Loperamide

In the short-term, loperamide is sometimes misused to lessen cravings and withdrawal symptoms; however, it can cause euphoria, similar to other opioids.

CONSIDERED OTC MEDICATION

Over-the-counter (OTC) medications are those that can be sold directly to people without a doctor's prescription. OTC medicines treat various diseases and their symptoms, including

- Pain
- Coughs and colds
- Diarrhoea
- Constipation

Benefits of OTC Medication:

The benefits of OTC medicines include easy and quick access to medication. OTC areavailable at any pharmacy and most supermarkets.

Over - the- counter (OTC) medicines are drugs you can buy without a prescription, some OTC medicine relieve aches, pains, and itches. Some prevent or cure

diseases, like tooth decay andathlete's foot.

OTC Medicines are acritical component in advancing consumer health because they allowpeople to treat or manage many health conditions conveniently and successfully.

1. Medicines are easily accessible.
2. Save money.
3. Saves time.
4. improved education of consumer.

decreased cost of third-party players. 6.increased autonomy of the patient.

FDA review over-the-counter (OTC) drugs

The review of OTC medications is primarily handled by the U.S. Food and Drug Administration's (FDA) Division of Drug Information (CDER), the Office of Drug Evaluation, and the Nonprescription Drug Advisory Committee. These teams evaluate and review OTC ingredients and labels.

Over-the-counter (OTC) drugs safe to use:

Most OTC medicines are safe to use when the package directions are followed, but they can still carry a risk, even though they do not require a prescription. There is the possibility of side effects, drug interactions, or harm due to excessive doses.

ADVANTAGES OF OTC DRUGS

- Benefits outweigh risk
- Low misuse& abuse potential
- Consumers are to:

Self-diagnoseSelf-treat
Self-manage

- Adequately labelled
- Health practitioner are not needed.

DISADVANTAGES

- Poorer compliances
- More difficult to study a drug's effect
- Misdiagnosis occurs.
- Reduced opportunities to receive counselling aboutPossible lifestyle therapies.

Reasons for OTC drug side effects:

- Inappropriate management of disease and symptoms might lead to unnecessary pharmaceutical use and associated side effects.
- Overuse and underuse of effective drugs can both result in catastrophicconsequences.
- A patient who receives an incorrect diagnosis and takes the wrong OTC medication may present with a potentially serious but treatable disease.2
- Unfavourable risk-benefit ratio.
- High potential for misuse and abuse.
- Lack of awareness by the consumer who is incapable to evaluate the safetyeffects mentioned on the drug.

OTC drugs – addiction

.OTC drug abuse has increased especially among teenagers and young adults. Many people use OTC drugs to self-medicate their symptoms at home. The misuse of drugs can lead to serious physical health problems, dependence, and addiction.

The following are the symptoms of OTC drug addiction:

- Using more of the drug than recommended.
- Lying about how much usage.
- Hiding medicines from others.
- Medicine stealing.

Once OTC drugs are addictive, they may even cause withdrawal symptoms when we stoptaking them. The symptoms may be categorized as mild, moderate, or, severe, based on drug type, how long it has been used, and dosage.

symptoms include:

- Nausea
- Agitation
- Confusion
- Mood changes
- Cravings
- Anxiety

Treatment for OTC drug addiction

If addicted to certain over-the-counter drugs, cognitive behavioural therapy and other forms of therapy have been successful in helping people from addiction, and detox is thefirst step of treatment.

Commonly misused OTC drugs :-

- Cough suppressants (Dextromethorphan)
- Pain relievers (Acetaminophen and Ibuprofen)
- Nasal decongestants (Pseudoephedrine)
- Antihistamine/Motion sickness (Dimenhydrinate and diphenhydramine)
- Caffeine
- Laxatives
- Diet pills (Ephedra)
- GI ailments like hyperacidity/constipation/diarrhoea/ nausea (Digene, Zinetac, Uri enzyme, Lomotil,

Dulcolax).

Díug Application Píocess

Under the drug application process, a sponsor of a nonprescription drug submitsa New Drug Application (NDA) or an **Abbreviated New Drug Application (ANDA)** to FDA for approval. The sponsor cannot market the nonprescription drug until FDA approves the NDA or ANDA.

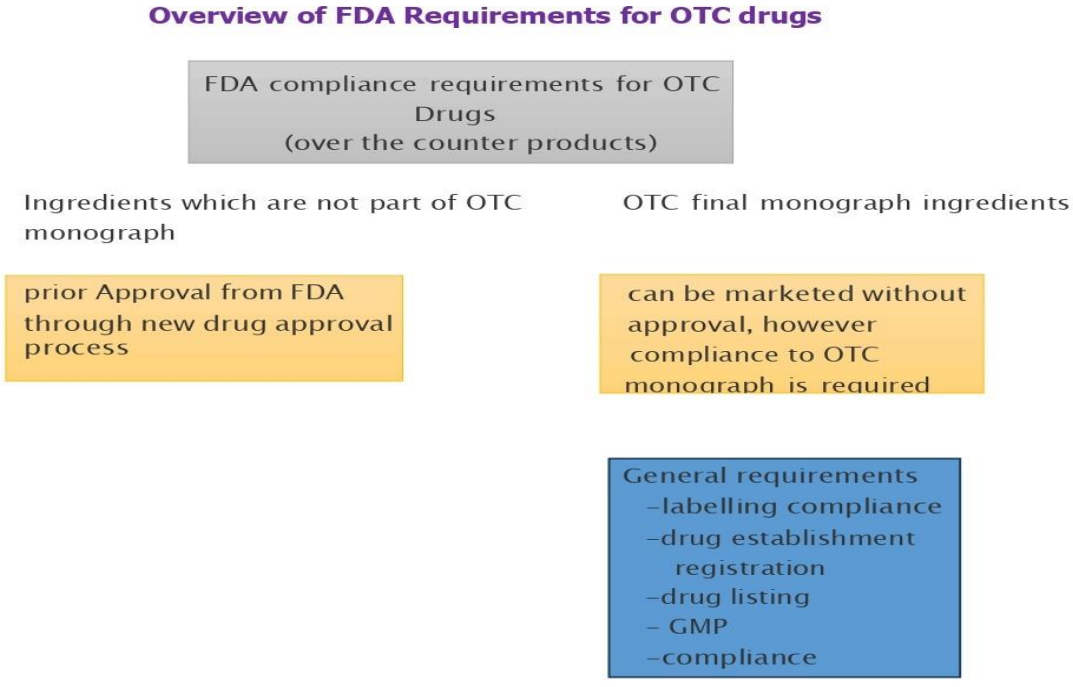
- **Maíkel'ing Pal'hways**
- Under the drug application process, a nonprescription drug may be marketed either: 1) direct-to-nonprescription (commonly referred to as direct-to-OTC)
  2) prescription-to-nonprescription switch (commonly referred to as Rx-to-OTC switch).
- **Diíecl'-l'o-Nonpíescíipl'ion**
- An NDA may be submitted to market a new drug as nonprescription (direct-to-OTC) without first receiving approval as a prescription drug.
- **Píescíipl'ion-l'o-Nonpíescíipl'ion Swil'ch**
- However, many nonprescription drugs that have an approved NDA or ANDA were first approved as prescription drugs, before eventually receiving FDA approval to be marketed as nonprescription (an Rx-to-OTC switch).

OTC LABEL

All nonprescription, over-the-counter (OTC) medicine labels have detailed usage andwarning information so consumers can properly choose and use the products.

Below is an example of what the OTC medicine label looks like.

- **Active Ingredient**. Therapeutic substance in product; amount of activeingredient per unit.
- **Uses**. Symptoms or diseases the product will treat or prevent.
- **Warnings**. When not to use the product; conditions that may require advicefrom a doctor before taking the product; possible interactions or side effects; when to stop taking the product and when to contact a doctor; if you are pregnant or breastfeeding, seek guidance from a health care professional; keep product out of children's reach.
- **Inactive Ingredients**. Substances such as Colours or Flavors.
- **Purpose**. Product action or category (such as antihistamine, antacid, orcough suppressant.
- **Directions**. Specific age categories, how much to take, how to take, and howoften and how long to take.
- The list of OTC monograph ingredients and FDA regulation for OTC drugs can be found in the 21 CFR Part 330.



FDA Requirements for OTC Drugs (OTC Monograph Product)-

1. Compliance with OTC monograph – Ingredients, concentration, and purpose should be in accordance with the OTC monograph.
2. OTC drug labelling – The content and format of the labelling should be in accordance with FDA OTC drug labelling requirements.
3. **Establishment Registration** – Manufacturing facilities involved in manufacturing, packing, and processing the drug must be registeredwith the FDA.
4. NDC drug listing – Drug listing is a mandatory requirement for all thedrug products marketed in the USA.
5. GMP (Good Manufacturing Practice) – Manufacturing of the product should be in accordance with Good Manufacturing Practice as defined in the 21 CFR210 and 211.
6. US Agent Appointment – Foreign facilities must appoint US Agent for FDA communication purposes.

- OTC sunscreen products must meet the additional requirements as perthe FDA guidance for OTC sunscreen products marketed without FDA approval.

- OTC drug manufacturers must also renew their drug establishment registration between 1st October to 31st December.

The Label Also Tells You.

- **The expiration date**, when applicable (date after which you should not usethe product).
- **Lot or batch code** (manufacturer information to help identify the product).
- **Name and address of manufacturer, packer, or distributor.**
- **Net quantity of contents** (how much of the product is in each package).
- **Other Information**. How to store the product properly and required information about certain ingredients (such as the amount of calcium, potassium, or sodium the product contains)

FDA Requirements for OTC Drugs (Over the Counter Products) And Understanding FDA Regulation for OTC Drugs

- FDA requirements for OTC drugs vary for OTC monograph productsand new OTC drugs.
- Drugs with active ingredients published in the OTC final monograph can be marketed without prior approval from FDA.
- However, if you plan to market OTC drugs with active ingredients that are not part of the OTC monograph, you should obtain FDA approval through the new drug approval process.

The list of OTC monograph ingredients and FDA regulation for OTCdrugs can be found in the 21 CFR Part 330

The manufacturers of OTC medicines sometimes make changes to their products or labelling **(**new ingredients, dosages, or warnings**)**. Make sure to read the label each time you use the product. Always look for special "flags" or "banners" on the front product label alerting you to such changes. If you read the label and still have questions, ask your doctor, pharmacist, or other health care professional for advice.

information, and instruction regarding the adverse drug reactions, dosage schedule of drugs to the patients and warning them about the unwanted effects of medicines and monitoring such unwanted effects

In the OTC drug marketing, the Customer and Consumer being the same, companies have to immediately address the information needs more effectively and on a continuous basis. The acceptability of OTC drugs will improve once the awareness level is enhanced.
When the knowledge of the traditional medicine is rooted in the culture, the knowledge about allopathic OTC drugs has to be disseminated by manufacturing company and ensure drastic reduction in the high information asymmetry existing today.

CONCLUSION:

Rational use of drugs is an important tool in the safe and effective treatment of patients. Indiscriminate uses of drugs not only waste scarce resources that could otherwise be spent on other essential services, but also leads to drug induced disease. One should avoid self-prescription of medication, and self-acquired remedies. A pharmacist can play a multidisciplinary approach to the promotion of the rational use of medicines by providing proper

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