

Brief Overview on Over-the-Counter Medicine and their Impact on Community Health

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ABSTRACT

Self-care and self-medication are common practices in any health care system. The 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 of common 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 Abuse are characterized as over-consumption beyond the approved medical practice or medical norms when the hazards and unfavorable 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 use. There is an urgent need to implement legislation to promote judicious and rational use of over-the-counter drugs.

Key words: Addiction, Drug Abuse, Self-medication, Misuse, Non-prescription drugs, Over-the-counter drugs, Regulations.

INTRODUCTION

Over-the-counter (OTC) drugs are the ones that are directly sold without the need of being presented with a prescription from a registered medical practitioner. We often approach a pharmacist than a physician for minor ailments like a cough and cold, headache, backache, toothache, muscular aches, menstrual cramps, fever, etc.¹ These OTC or non-prescription drugs are considered to be safe and effective, and readily available to the general public without a doctor's prescription. These are used primarily for symptomatic relief and not as substitutes for prescription drugs.² They play an increasingly vital role in our self-care system and are the most prevalent means of treating majority of common health problems. These OTC drugs save time in medical centers, saves high consultancy fees as well as save time from the long queues at the doctor's office.³ Irrational use of these medications has raised concern among the medical fraternity

regarding the safety of their self-medicating patients. These concerns have rapidly increased due to improper knowledge of adverse effects such as antibiotic resistance, skin problem, hypersensitivity, and allergy.^{4,5} Many young adults and adolescents purchase and use OTC drugs, and some of them may take these drugs without reading the directions to use them.⁶ Significant problems and malpractices were identified with OTC drugs like sharing of OTC drugs, expired medicine usage, doubling the drug dose when they are ineffective, OTC storage, and not reading labels and expiry dates.⁷

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

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included in some OTC products without notifying the users.⁸ 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.⁵

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 drugs were 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.⁹

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 morbidity rate) and economic damage.¹¹ 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.¹⁰ 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.⁵ In contrast to prescription, OTC drugs are not defined as a distinct category of drugs. 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.¹² 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. It further

recommended that the Ahooja Committee should identify the OTC drugs list, along with conditions, and frame the draft for amending the D&C Rules.¹³

Reasons for self-medication

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 centers
6. Lack of trust in doctors
7. Nurse advice
8. Pharmacist recommendation
9. Poverty, ignorance, misbeliefs
10. Extensive advertisement
11. Availability of drugs other than in Pharmacy
12. Other reasons.⁴

Choosing and using over the counter drugs

Consumers often self-diagnose their ailment and tend to prescribe their own medications which increases the risk for errors. For example, in rare cases a simple headache might be an early warning of a brain tumor or hemorrhage while most headaches are not dangerous, this misdiagnosis can lead to serious complications. Similarly, a severe heartburn may signal an impending heart attack. Ultimately people must be more cautious when determining if their symptom or requires medical attention by a physician or pharmacist.⁹

The guidelines for choosing on using OTC drugs are as follows

- While self-diagnosing makes sure it is as accurate as possible, and not based on assumption to avoid further health complications.

- Select products with few and appropriate ingredients and does not contain any allergens. More active ingredients lead to unnecessary drugs which in turn increases the risk and treatment cost.
- Read label carefully to determine the correct doses, their side effects and contraindications.
- Consult a pharmacist or physician about the medication, whenever in doubt.
- Check for possible drug-drug interactions with other drugs in case of polypharmacy.
- Strictly adhere to the recommended dose, consult a pharmacist or the doctor if the symptoms do not subside.
- Never consume the OTC drugs beyond the maximum time suggested. Immediately consult a pharmacist or a physician if the condition does not improve.⁹

Effects of over-the-counter -drugs on health

Inappropriate medication usage is clinically unwelcome because it exposes the user to damage without their knowledge. There is no guarantee of benefit, and it could be harmful in different ways (Table 1). Concerns regarding undesirable effects of OTC due to dependence [particularly on sedatives, laxatives, analgesics, and antacids] and medication resistance are increasing rapidly.⁵ Abuse and misuse of OTC is not widely documented in India hence.¹⁴

The use of OTC epinephrine is considered to be safe and effective in low doses but they can severely harm when mishandled or abused. Death can be a leading possible outcomes.¹ In Finland, few community pharmacies observed that vitamins and natural medication comprised 9% of drug-related problems, among which lactic acid bacteria preparations were commonly mentioned product category.¹⁵

Dextromethorphan [DXM] has surpassed codeine because of its availability, higher efficacy, and low toxicity profile at indicated dosages and is an extensively used cough suppressant. Since DXM is easily available as OTC cough syrup they are vulnerable to misuse for their psychosis effects (delusions, hallucinations, and paranoia) when overdosed [1500 mg\ day].¹⁶ Loperamide is occasionally used to alleviate cravings and withdrawal symptoms for a short time; however, like other opioids, it can promote euphoria. Misuse of Loperamide can cause dizziness, nausea, constipation, ocular changes, and

loss of consciousness. It can induce irregular or rapid heartbeats, as well as kidney disorders.⁸

OTC painkillers like Ibuprofen and codeine are blamed for the deaths of 49-year-old and 41-year-old consumers who died of renal failure and respiratory depression respectively, due to OTC addiction, according to recent coroner's inquests. Due to safety reasons, few OTC drugs are withdrawn from the market like Co-proxamol, an analgesic combination containing the opioid dextropropoxyphene and paracetamol.² Reports claim that acetylsalicylic acid can have an unfavorable effect on thrombocyte activity even at low dosages. Treatment for acetylsalicylic acid poisoning is particularly critical with manipulation processes like cold water extraction which helps remove toxins.³

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 catastrophic consequences.
- 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 safety effects mentioned on the drug.
- Inadequate labeling of OTC products.
- Low socio-economic strata.
- Use of multiple medications – polypharmacy.⁵

OTC drugs – addiction

According to data from the Substance Abuse and Mental Health Services Administration [SAMHSA] in the US, approximately 3.1 million persons aged 12 and older have misused OTC drugs at least once in their lives.

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. People misusing OTC drugs can move on to other prescription painkillers or marijuana in search of a stronger high.^{17,18}

Table 1: Commonly seen OTCs and their adverse effects.²

Symptoms	Medications	Adverse Effects
Cough / Cold / Fever	Chlorpheniramine maleate, Phenylephrine, Pheniramine, Paracetamol	Drowsiness, dry mouth, headache, fatigue, nausea, loss of appetite, increased heart rate
Headaches / Body aches / sprains	Ibuprofen, Ibuprofen+Paracetamol, Diclofenac	Nausea, headache, confusion, fluid retention, dizziness, abdominal pain
GI ailments like hyperacidity / constipation / diarrhea / nausea	Psyllium, Methyl cellulose, Polycarbophil	Constipation, dizziness, headache, abdominal pain,
Pain relievers	Acetaminophen, ibuprofen	Constipation, liver damage, drowsiness, addiction risk, allergic reactions
Nasal decongestants	Pseudoephedrine	Restlessness, rapid heart rate, insomnia, anxiety, high blood pressure
Motion sickness pills	Dimenhydrinate and Diphenhydramine	Drowsiness, constipation, blurred vision, dry mouth/nose/throat

Not all OTC drugs have the potential to cause addiction but some drugs do. The misuse of Dextromethorphan and Loperamide can lead to addiction according to National Institute on Drug Abuse. OTC drug addiction may be through chronic, long-term abuse and results in severe health problems, work problems, or problems at school. Accidental overdose risk is high and it can be life-threatening and cause long-term damage to the brain and the body. OTC drugs whether moderately or severely abused, there are risks. With many drugs, the more the drug use, the more the body desires, causing increased tolerance and addiction.^{17,18}

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.
- Continuous use of medicines, irrespective of negative consequences.
- Buying medicine in bulk out of fear that it may run out.^{17,18}

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

- Nausea
- Agitation
- Confusion

- Mood changes
- Cravings
- Anxiety

Treatment for OTC drug addiction

If addicted to certain over-the-counter drugs, cognitive behavioral therapy and other forms of therapy have been successful in helping people from addiction, and detox is the first step of treatment.¹⁷⁻¹⁹

OTC drug Detox

This program provides medical management of withdrawal symptoms to prevent severe withdrawal symptoms and medical emergencies. This program also provides clinical support to overcome the OTC drug withdrawal psychological effects.^{17,18}

OTC drug rehab

Rehab program also help provide structural and ongoing support to kick substance abuse habits for good. They also provide behavioral therapy and support to make positive life changes to overcome addictive behaviors.

The most common approaches of OTC addiction treatment are:^{17,18}

- Educational seminars
- Behavioral therapy
- Recovery support group
- Life skills development

Treatment for OTC overdose

Taking too many OTC medicines can lead to liver damage,

stomach bleeding, and kidney diseases. For taking an OTC medication first, it's important to know what kind of pain reliever you're taking. OTC pain relievers are available as two major classes – Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and acetaminophen.³ Nearly one in four patients show they exceed the recommended dose of acetaminophen on one or more common OTC products, and 5 % dosed out amounts that could cause serious harm (> 6 grams). In addition, nearly half of patients overdose by double-dipping with two OTC medications containing acetaminophen.²⁰ Acetaminophen and NSAIDs have mostly overdosed as OTC drugs.²¹ With many prescription medications switching to OTC drugs the consumption of OTC products appears to be increasing. Older adults are the largest consumers of OTC medications, taking on average 4 OTC medications per day which may also lead to heart failure in some cases.²²

- **Avoid double dosing:** OTC pain killers and fever reducing agents are safe and effective when taken as per the instructions. Always ensured not to consume medications with similar active ingredients. If such a scenario occurs it'll be a case of a double dose. It is also important to consult a doctor about other past medical problems and medications or supplements being consumed.⁷
- **Read drug labels:** Drug labels include the list of active and inactive ingredients present and provide instructions on their usage. In case of queries regarding medicine, consult a doctor or a pharmacist.⁷
- **Overdose:** Signs and symptoms may not be seen initially but may cause nausea or vomiting, heartburn, abdominal pain, constipation, dizziness, fatigue, bleeding or bruising, jaundice, confusion, fever.⁷

All labels should be read properly and taken only as directed, over-dosing or using them for a longer time than indicated should be strictly avoided. In case of ambiguity on how to use an OTC drug, consult a physician or a pharmacist.

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/diarrhea/nausea (Digene, Zinetac, Uri enzyme, Lomotil, Dulcolax).
- Skin ailments like acne, rashes, cuts, and burns (Aiol, Caladryl, Betadine Candid, Flutivate, and Soframycin).
- Nutritional supplements (Becosules, Coba Dex, Shelcal, Protinex, Ferrodal).¹⁷⁻¹⁹

OTC intake under supervision

Drugs that reach the safety and efficacy standards are accredited for self-medication as OTC. However, their inappropriate use or misuse due to lack of knowledge and understanding can lead to serious complications, especially in adolescents, older adults, and vulnerable populations like pregnant and lactating women.¹¹ Prevalence of self-medication is observed higher in adults and older adults either with OTC or home remedies for minor ailments.²³

Toddlers and Children: Drug treatment in children differs from that in adults, the pediatric drug dosing is usually based on weight or surface area. The parent is usually unaware of the child's doses and tends to administer the normal adult dose.²⁴ This lack of proper knowledge can lead to over or under dose, leading to serious complications. Frequent self-medication could not only hinder their development, but also lead to serious problems such as drug resistance, and different toxic effects.²⁵

Senior Adults

As polypharmacy is commonly seen in senior adults, self-medication can be of great concern as there is an added risk of interaction between hidden active ingredients of OTC drugs and prescription medicines which contributes to unfavorable health conditions (drug resistance, adverse effects, drug-interactions, including death)²⁶ which can worsen the existing disease state. Common self-medicating drugs among senior adults are central action muscle relaxants, analgesics and antipyretics, and non-steroidal anti-inflammatory and anti-rheumatic agents.²⁷ Since most of the elderly self-medicators are unaware of the possible ADR due to their altered physiological parameters, it is an imperative duty of the doctor or the pharmacist to enquire regarding the history of self-medication while prescribing or dispensing the

medicine to avoid any drug-drug interaction or drug-disease interaction.²⁸

Pregnant and Lactating Women: An extremely important issue in this discussion is the use of OTC drugs by pregnant and lactating women. Specifically, pregnant individuals must be very cautious while using the same. Unfortunately, there are several reports stressing the fact that in spite of a lot of efforts by healthcare professionals, extensive self-medication in pregnant ladies is rampant, especially in India or developing countries, where they are easily available.²⁹ Cross-sectional study conducted among pregnant ladies in Sharjah showed 40% of them using OTC drugs with the potential to cause side effects of concern in them. Many of these drugs do not have adequate studies to prove their safety during pregnancy such as certain antimicrobials, antiemetics, analgesics, etc. which should be used only under the guidance of an RMP.³⁰ FDA has classified drugs by pregnancy risk. Only a few OTC medications or prescription drugs come under the category A or B (indicating no evidence of risk to the fetus). Due to the vulnerability of these populations, they are usually excluded from various clinical trials and hence no or fewer safety data is available.³¹

Necessary criteria for making OTC medicines available

To get approval to change a prescription drug to OTC, the manufacturer of the product must define the medication's efficacy and safety. Generally, drugs can be OTC if they are least possible for misuse and abuse.³² Initially, drugs are available for consumption for the general public only on obtaining a prescription after consultation. However, to reinforce consumer access to a secure and effective drug, it's possible to switch an equivalent drug to OTC status after safety, effectiveness, and ease of use of the drug is verified.⁵ There are three necessary criteria for making medicines available as OTC:³²

- **Diagnosis:** The patient should be able to make the diagnosis. For example, hay fever is easily diagnosed and effective medicines like antihistamines are available as OTC. But in some cases, patients may need counseling from the pharmacist, like various histamine H₂ receptor antagonists, are available OTC for short-term symptomatic relief to heartburn, dyspepsia, acidity. The diagnosis for these is not difficult but a pharmacist would recommend seeing a doctor if the person is buying these drugs repeatedly.
- **Efficacy:** A medicine is sold as OTC because it is considered sufficiently safe, without considering its

efficacy. OTC drugs aim to provide the maximum efficacy with the lowest dose possible to ensure safety.

- **Safety:** OTC drugs focus on safety more than efficacy to avoid complications due to self-medication. If a medication can cause an adverse effect, it should not be made available as OTC. Antihistamines and Astemizole were withdrawn from OTC drugs when it was known to cause ventricular arrhythmias. Limiting the dosage strengths of OTC formulations may reduce unwanted effects.³²

Other criteria for making the medicines OTC include improved and rapid accessibility and shifting costs.³² To switch prescription version of a drug to OTC, the drug must have some characteristics that cause it to be suggestive of self-medication, and they are as follows:⁵

- The symptom for medication-assisted treatment should be easily recognizable
- The drug should possess a higher safety margin
- The drug should be easy to administer and show its effect rapidly after administration
- The drug should not be addictive or narcotic
- The use of drugs should not mask any underlying potentially dangerous conditions

The advantage of OTC medicines is that they provide a convenient means for patients to self-treat their minor causes like fever, allergies, and headache.⁵ OTC products are available for lower price than their prescription alternatives to ensure larger volumes of sales.³² OTC drugs allow faster and cheaper access to healthcare.⁵ For switching RX to OTC drugs sale volume should be high and highly used by the customer, a drug's status is changed to OTC drugs when that drug is used as R_x for many years (this vary from country to country), the PMS data should show the drug with no serious side effects.⁵

CONCLUSION

In any health-care system, self-care and self-medication are key components. The self-medication procedure includes the usage of over-the-counter (OTC) drugs. Pain, cough and cold, diarrhea, constipation, acne, and other common ailments and symptoms are all treated with over-the-counter drugs. Some OTC drugs contain active components that could be abused if used in higher-than-recommended doses. Codeine-based (primarily compound analgesic) drugs, cough products (particularly dextromethorphan), sedatives,

decongestants, and laxatives identified as the five main classes for self-medication. The popularity of over-the-counter drugs among patients may raise their abuse potential. Physiological or psychological harm (e.g., narcotic addiction), harm from another chemical (e.g., NSAID-related stomach bleed), and social and economic concerns were among the connected harms. Pharmacist vigilance and patient counseling can aid in the reduction of over-the-counter pharmaceutical abuse. Limiting supplies, promoting awareness among public and professionals, and utilizing existing support and services are among the strategies and actions used, while linked studies are insufficient. To inform policy, legislation, and interventions, more research should be conducted to quantify the scope of abuse, evaluate managements, and record individual experiences.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

ADR: Adverse Drug Reaction; **DCC:** Drug Consultative Committee; **DXM:** Dextromethorphan; **FDA:** Food and Drug Administration; **FDC Act:** Food, Drug and Cosmetic Act; **NSAIDS:** Non-steroidal anti-inflammatory drugs; **OTC:** Over-the-counter; **PMS:** Post Marketing Surveillance; **RMP:** Registered Medical Practitioner; **Rx:** Medical Prescription or to take; **SAMHSA:** Substance abuse and Mental Health Services Administration.

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