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# A Review on Over the Counter Medication

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**Abstract:** *Over-the-counter (OTC) medications constitute an essential component of modern healthcare systems by enabling convenient, accessible, and cost-effective treatment of minor illnesses without the need for a medical prescription. These products are formulated and regulated to ensure a favourable benefit–risk profile, allowing safe self-medication when used as directed. Their increasing global demand is driven by rising health awareness, improved regulatory frameworks, and the growing emphasis on patient-centred care. However, inappropriate use of OTC drugs—such as overuse, drug interactions, polypharmacy, and misuse—poses potential risks, highlighting the need for pharmacist-guided counselling and strict adherence to regulatory standards. This review summarises the classification, regulatory status, advantages, challenges, and public health significance of OTC medications, underscoring their role in promoting responsible self-care and reducing the burden on healthcare systems*

**Keywords**: OTC medication, Prescription, U.S, Paracetamol

## I. INTRODUCTION

The increasing cost of healthcare and the rising trend of self-medication drive the increased use of over-the-counter (OTC) medicines.The most popular OTC remedies relieve symptoms of colds and allergies and associated congestion.These OTC remedies typically include analgesics such as acetaminophen or ibuprofen to relieve pain and sedative antihistamines such as diphenylhydramine (Benadryl) or doxylamine (NyQuil) to suppress allergic reactions.[1]

The act of taking medication on one's own initiative or at the recommendation of a friend, relative, or other person without first visiting a qualified healthcare provider is known as self-medication. Patients save time and money by switching from prescription to over-the-counter (OTC) medication since it is less expensive for them to buy OTC than to fill a there are additional factors that may lead patients to choose self-medication, such as prior acute illness experience, drug knowledge and usage, and the lack of access to medical professionals for patient care.[2]

In 1970 The World Federation of Proprietary Medicine Manufactures Association renamed as World Self-Medication industry (WSMI) with a primary objective to reduce the work load of regulation of medicine and then classifies medicines into two: Prescription and non-prescription. The new era of self-medication starts from 1980's, were prescription began to be switched to non-prescription drugs. Ibuprofen was the first drug that was switched into non-prescription used for pain, in UK (1983) and in US (1984).[3]

Based on information from the National Hospital Morbidity Database in Australia, young adults appear to be at high risk of paracetamol related harm, with 4577 cases of paracetamol toxicity being recorded in 2017.Paracetamol was the most frequently used in overdoses, and a 108% increase in acute liver toxicity was reported between 2007 and 2017.[4]

The availability of OTC for self-medication in the U.S. healthcare system saved $102 billion annually, including $25 billion in drug cost savings and $77 billion from clinical visits.This accelerating trend and economic benefits are posing a considerable impact worldwide, specifically in developing countries like India. An Indian study investigating the 'Value of OTC in India' reported approximately Rs.30,730 cr annual savings and improvement in overall health outcomes.[5]

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**Figure No. 1:- OTC Medicine**[6]

### I.I TYPES OF OTC MEDICINE

OTC medications come in numerous varieties. Store brands are widespread, and brand names are subject to change. To find out what the active ingredients are in any product, read the labels. OTC medication categories include:[7]

**Antihistamine:-** These relieve allergy-related runny noses, itchy eyes, and sneezing (but not colds). Some may put your kids to sleep. Children under the age of two should not use these. Use only in infants or children with asthma with a doctor's approval. These medications consist of loratadine, diphenhydramine, and chlorpheniramine.

**Cough suppresant :-** World Journal of Pharmaceutical Research These suppress the body's coughing reflex. In order to remove bacteria and mucus from the lungs, coughing is necessary. A healthcare professional should be consulted before giving your child a cough suppressant.

**Decongestant:-** These can ease congestion brought on by colds or allergies. To facilitate breathing, they achieve this by constricting the inner portions of the nose. Never use them for more than two or three days in a row. Oral decongestants may cause a variety of adverse effects. These include feeling agitated, restless, and lightheaded.

**Anti-diarrhea :-**Often, these medications are not necessary. If your child has diarrhoea, take them to the doctor. Don't forget to give your kids lots of water. Before giving your child these medications, consult with their healthcare professional. Give no medication containing bismuth subsalicylate to a kid under the age of 19. Give no medication containing loperamide to a child under the age of two.

**Laxatives :-**These aid in constipation relief. They function in various ways. To make their poop more substantial, some people add fibre or water. The intestines may find it easier to move as a result. To make the stool more slick, some are applied to its surface. Some help the faeces pass more readily by softening it. Others result in a stronger movement of the intestines. Give no laxatives to infants or kids without first consulting your child's doctor. Mineral oil, psyllium, magnesium hydroxide, and glycerin suppositories are examples of laxatives.[8]

### I.II ROLE OF PHARMACIST IN OTC MEDICATION[9]

Pharmacists play an essential role in health care services, specifically in rural areas where physicians are not readily available. The community pharmacy service area is the only lifeline of the healthcare system or where primary care physician services are excessively high-priced. Moreover, Rx-to-OTC switches generate more possibilities for a pharmacist to serve the community by offering primary health care services to consumers.

Considering the increased accessibility of OTC medicines, role of pharmacists to monitor the potentially inappropriate use of OTC medicines has been increased. The pharmacist's role is not only limited to monitor or suggest a safe and appropriate option tailored to customers' need but may also advise an option related to non-pharmacological

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approaches, where medication seems to be avoidable. Moreover, pharmacist's role to promote affordability is also vital by recommending a generic version as per consumer need.

**Figure No.2 :- Role of pharmacist**[10]

**I.III REASONS FOR MEDICATION**[11]

- Having a previous prescription
- Saving time
- Family member's advice
- High price of doctor's visit
- Crowded medical centers
- Lack of trust in doctors
- Nurse advice
- Pharmacist recommendation
- Poverty, ignorance, misbeliefs
- Extensive advertisement
- Availability of drugs other than in Pharmacy
- Other reasons.

## II. EFFECTIVENESS OF OTC MEDICATION

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.[12]

Effectiveness had been previously defined as the ability of an OTC medicine to produce symptom relief. Questionnaire wording was adapted (and expanded) from various reports , with one using a six-point scale (not at all effective to very effective). A 10-point scale has been used to evaluate a decision-support system to improve the safe use of OTC medicines. For the current study, perceived effectiveness was determined by a 10-point scale with worded-anchoring at the poles (1 = not effective and 10 = very effective).[13]

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].

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. Reports claim that acetylsalicylic acid can

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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.[14]

## III. SIDE EFFECTS OF OTC MEDICATION

Inappropriate management of disease and symptoms might lead to unnecessary pharmaceutical use and associated side effects.[15]

The Colombian Fertility and Contraceptive Use Survey found that 51% of OTC users and 44.4% of clinic users reported any side effect from initial OC use. Neither group reported the most important complications of OC use (thrombophlebitis and thromboembolism), and similar proportions reported the most common side effect (headache). OTC users were more likely to mention nervousness, skin problems, pain and bleeding problems, while clinic users were more likely to complain of weight changes, varices and other side effects (not specified).[16]

Increased chance of stroke or heart attack

- Gastrointestinal issues
- Liver and kidney damage
- Dehydration, hallucinations
- Depression and anxiety.[17]

Codeine abusers and dependents were either acute side effects such as urticarial itching, distorted vision and respiratory depression or chronic side effects such as nausea, constipation, liver, bowel kidney failure, anaemia, seizures, ulcers and swollence the reach of healthcare to all and act as the future growth drivers because rural markets are still unexplored markets for OTC medicines.[18]

## AVAILABILITY AND AFFORDABILITY OF OTC MEDICATION

It has already been stated that around 67% of the Indian population currently lives in rural areas. Still, rural markets contribute only 17% of the sales, suggestive of limited access to OTC medicines. This could be a huge opportunity for improving access in rural settings that could enhance the reach of healthcare to all and act as the future growth drivers because rural markets are still unexplored markets for OTC medicines.[19]

Availability of medicines was very poor in public sector facilities, which are the primary source of free medicines for a majority of India's low-income population. Availability of medicines is better in private retail pharmacies but affordability remains a big challenge for a majority of the population.[20]

Availability of medicines was 45.2 % and 51.1 % in Punjab and Haryana respectively. Availability of anti-hypertensives was around 60 % in both the states whereas for anti-diabetics it was 44 % and 47 % in Punjab and Haryana respectively.[21]

## DOSAGE INDICATIONS AND RISK OF MISUSE

Medication "misuse" refers to the improper use of over-the-counter drugs. The improper use of over-the-counter medications for a known medical condition is known as misuse.[22]

- 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 (Airol, Caladryl, Betadine Candid, Flutivate, and Soframycin).[23]

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Pharmacists explained how they use consumer behaviors, attitudes, and established protocols to spot instances of overuse or abuse. According to the majority of pharmacists, abusers or misusers could be immediately identified by their physical attributes, behaviors during talks, and facial expressions.

A lot of pharmacists also believed that frequent visits, making the same product request, requesting a lot at once, going to the pharmacy during peak hours, taking advantage of the crowd to avoid being asked, and refusing any other option were all common behaviors that helped identify instances of misuse and abuse. A small percentage of pharmacists reported that some patients tell them about the medication's illegal use.

When asked how they identify problematic use of over-the-counter medications, almost half of pharmacists mentioned the pharmacy mnemonics WWHAM (which stands for five questions).

W = Who is the patient?

W= What are the symptoms?

H = How long have the symptoms been present?

A = Action taken,

M = Medication being taken.[24]

Harms resulting from misuse, abuse, and dependence on OTC medicines generally included; physical, psychological, social and financial harm, decreased health-related quality of life (HRQoL), hospitalisation, and death. Harms related to codeine-based analgesics' abuse and dependence were more frequently reported than other OTC medicines in the reviewed studies.[25]

Self-medication and prescriptions have increased during the pandemic due to increased misinformation, a lack of prescribing doctors knowledgeable about disease pathology and the most recent evidence, and the added fear of an unidentified demonic disease. Up to 66% of people report getting drugs without a prescription. Self-medication undervalues illness incidence and prevalence. It affects institutional policies designed to lessen the diseases, particularly in a pandemic where contact tracing and prompt case documentation are essential.[26]

## IV. PRESCRIBED MEDICATIONS AND OTC MEDICATION

The drugs are classified into prescription or non-prescription drug categories based on their inherent toxicity, intended use, dosage form, posology, and safety. The drug's safety information obtained from market experiences plays a significant role in reclassifying the drug in a downward or upward status. Drugs for catastrophic diseases are mainly categorized in the prescription drug category, thus, consistently regulated throughout their lifecycle in contrast to the non-prescription drug category (OTC).

A new drug application (NDA) may be" submitted for a direct-to-OTC drug product. However, many FDA-approved OTC drug products (i.e., OTC products that have an approved NDA) begin their lifecycle as NDA-approved prescription drugs and eventually switch to OTC status under the NDA provisions. This process is commonly referred to as an Rx-toOTC switch. However, switching a new chemical entity or a prescription product, which meets the essential criteria of inherent toxicity, intended use, dosage form, posology, and safety, requires the following additional criteria to advocate the change of status to non-prescription sale.[27]

In addition to being demonstrated to be reasonably safe and well tolerated, over-thecounter medications must be used primarily to treat conditions for which a doctor is not directly supervising the patient. While some areas allow the sale of OTC drugs like codeine, most other drugs must have little to no potential for abuse.[28] Extensive or high-volume use of product.[29]

During a period of three to six years, prescription drugs that demonstrate their safety and suitability as OTC medications may eventually be converted back to prescription. Diphenhydramine, an antihistamine that was formerly only available with a prescription but is now sold over the counter almost everywhere, is an example of this. Cimetidine and loratadine in the US and ibuprofen in Australia are more recent examples.[30]

The product has been prescription marketed for at least five continuous years in the same country in sufficient quantity. However, the appropriate time considered on prescription for a product may varies for example, up to 10 years in the Philippines, 6 years in Japan, 3 years in New Zealand and no time specified in the European Union. In India, a new drug shall continue to be considered as new drug for a period of 4 years from the date of its first approval. The basic

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notion of 5 years of prescription marketing is based upon the fact that with the help of effective safety monitoring system, the adverse events associated with products have been recognized in the firstyears. Its adverse events give no cause for concern, and their frequency has not increased unduly during the marketing period.[31]

## V. SCENARIO OF OTC MEDICINE

**Status of OTC medicines in the United States Status**

In the U.S., there are more than 80 classes of OTC medications amounting to up to 1,00,000 marketed products. It is estimated that every year, OTC drugs save $102 billions in US of which 25 billion is saved due to their use and $77 billion is saved as unnecessary hospital visits are avoided. According to the US FDA, OTC drugs should fulfil the following criteria: favorable benefit-risk ratio, low potential for misuse and abuse, consumer awareness regarding its use, and adequate labeling. The switch to OTC category needs an elaborate OTC medicine review process. Some examples of medicines that experienced a switch from prescription medicine to OTC in the US include triamcinolone acetonide, fluticasone (spray), loratidine, fexofenadine, topical antifungals, pseudoephedrine, loperamide, and ketoconazole. In the US, OTC medicines are marketed under regulations referred to as "OTC monographs." The medicines that do not fit within a specific monograph require approval via the New Drug Application (NDA) process.Some of the accepted OTC Drug Categories as per USFDA are antacids, antidiarrheal products, antiemetic, antiperspirants, cough and cold products, wart removers, sleep medications, ophthalmic products, products for piles, dandruff, dental caries, and analgesics. In the US, OTC drug advertising in media is permitted by law. The most commonly used over-the-counter (OTC) medicines in the United States recently are pain relievers, primarily acetaminophen (Tylenol) and ibuprofen (Advil, Motrin IB).

**Status in European union (EU) countries**

European Medicines Agency (EMA) has classified medicinal products into two categories as per article 70: prescription medicines and nonprescription medicines.Nonprescription medicines are divided into pharmacy medicines and general sales medicines in UK and Germany. Although pharmacy medicines are sold without a prescription, they are not available for self-selection and should be sold under the supervision of a registered pharmacist. Germany contributes maximum shares to the OTC market in Europe. All nonprescription medicines can be advertised in these 2 countries. In France, nonprescription medicines are divided into those that can be advertised to the public and those that cannot be advertised. In the year 2004, United Kingdom became the very first country in the world to include statins in the category of pharmacy-supervised OTC medicines. Since the availability of Simvastatin 10 mg tablets over the counter, its use in the UK has increased significantly. A policy guidance document published in 2006 states that OTC medicines should have a low risk of serious type A reactions and very low risk of serious type B reactions. In addition, they should not have interactions with commonly used medicines, which can produce serious adverse reactions.

**Japan**

The country has an extensive OTC market and it has contributed significantly to the worldwide OTC sales. Just like other consumer goods, OTC medicines in Japan can be freely advertised. Nonprescription medicines are further divided into those requiring guidance (post marketing surveillance is needed), type 1 (high potential risk), type 2 (less potential risk), and type 3 (relatively low risk). Type 1 OTC medicines can only be sold under the supervision of a registered pharmacist. Information about type 2 OTC medicines can be provided by a pharmacist or even by a qualified drug seller. Type 3 OTC medicines can be purchased at convenience stores and supermarkets. Pain relievers like Eve A EX and Bufferin, cold medicines such as Pabron Gold and Shin Lulu-A, and stomach remedies like Seirogan and Cabagin.

**Australia**

In Australia, OTC medicines are a separate category in the drug regulations and they are further divided into 3 categories: Pharmacy medications, pharmacist only medications, and general sales medications. The sale of pharmacy medications has to be restricted to registered pharmacies but the sales process can be shouldered by a nonpharmacist employee. Pharmacist only medications require a direct involvement by the pharmacist in the form of advice given on

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the appropriate use of medication. General sales medicines can be sold in nonpharmacy outlets.Advertising is allowed for OTC medicines in Australia. The most commonly used over-the-counter (OTC) medicine is paracetamol. Other frequently used OTC medicines for pain relief include non-steroidal anti-inflammatory drugs (NSAIDs) like ibuprofen and aspirin.

**China**

Since 1999, China has regulated the administration of OTC medicines. There is a separate manual for OTC medicines with a logo to mark this as a special category. In China, OTC drug advertisements are permitted on any kind of media, provided prior approval for the same has been obtained.[43]The most widely used over-the-counter (OTC) medicines recently are non-steroidal anti-inflammatory drugs (NSAIDs) and vitamins/minerals.

**India**

When come to the Indian scenario, in India the term OTC has no legal recognition and does not find a mention in the Drugs and Cosmetic Act(DCA)1940 or the Drug and Cosmetic Rules(DCR)1945.In India these medicines' are manufacture, import and sales are govern by DCR and DRA, under the supervision of Central Drug Standard Control Organization(CDSCO) which is headed by the Drug Control General of India(DCGI).The OTC committee of the Organization of Pharmaceutical Procedures of India(OPPI)works for the promotion of responsible self-medication to promote the OTC market. It not only for the promotion also ensures the safety. And the committee aims at community education and awareness programs.

In schedule H and X, prescription only drugs are listed out. In schedule G do not need a medical supervision but contain a "caution; it is dangerous to take this prescription except under medical supervision". The schedule K do not described as 'prescription only drugs' so the list of drugs consider as "OTC medicines". There are three class of medicines based upon the availability, Prescription only, pharmacy only and medicines on the general sales list. Any drug or preparation, not included in the first and third categories falls into the pharmacy only list. Medicines available in the second and third categories are often referred to as over-the-counter or OTC medicines In global OTC market, India ranks 11thposition. The most commonly used over-the-counter (OTC) medicines recently fall primarily into the categories of pain relievers (analgesics), fever reducers (antipyretics), and cough/cold remedies. The high acceptability and wide range of medicine availability will increase the OTC medicine production and use in India. But surveys shows that India become the 3rd rank within 5 years.[32]

Growing consumer demand for OTC products can be witnessed through an inevitable surge in OTC drugs sale across the globe, especially during the pandemic that further exhibits the significant extent of their utilization. As a result, in 2021, the global OTC market size was worth USD 157.0 billion and is supposed to grow at a compound annual growth rate (CAGR) of 5.8% to reach USD 233.6 billion by 2028.[33]

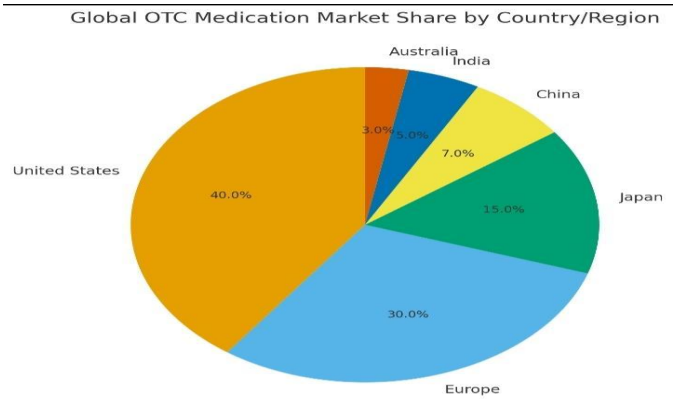


**Figure No.3 :- Global OTC Medication** [34]

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## VI. CONCLUSION

Over-the-counter (OTC) medications have become an integral part of modern healthcare systems worldwide. They allow individuals to manage minor health issues conveniently and efficiently without the need for a doctor's prescription. Common ailments such as headaches, colds, allergies, digestive discomfort, and minor skin problems can often be treated effectively using OTC products. This accessibility not only saves time but also reduces the burden on healthcare professionals and medical facilities, enabling them to focus more on serious and chronic health conditions. It promotes health awareness and helps people make informed decisions about managing common illnesses.However, while OTC medicines offer many advantages, their misuse or overuse can lead to significant health risks. While countries like the U.S., Japan, and Australia have strong OTC regulations, India's market is still developing but growing rapidly.

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