**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, with addiction 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 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 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 limiting supplies, raising public and professional awareness and using existing services and Internet The public generally believes OTC medicines to be helpful for treating minor ailments.

1. **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 terms kused 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” in India 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 to OTC 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 category of 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 OTC category, 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.

1. **OTC DRUGS:**

“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 physician need 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 patient medicines.
* 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 of medicines 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:**

* Prescription controlled medication.
* Prescription uncontrolled medication.
* Prescription controlled medication: this class involves the drugs and 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.’’

**TYPES OF OTC MEDICATIONS**

* DRUGS ANALGESICS
* ANTIBIOTICS
* COUGH SUPPRESSANTS
* ANTI ACNE DRUGS
* NSAIDS
* ANTISEPTICS
* DECONGESTANTS
* ANTACIDS
* ANTIFUNGALS
* ANTI HISTAMINE
* SMOKING CESSATION TOPICAL 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 common terms 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 cigarettes or 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 are caused 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 from a illicit drug dose overdose.

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

**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, the risk virtually didapper.
* Pharmacists should have to counsel every Patient on the safe and effective use of OTC 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.

1. **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 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.

1. **REFERENCE:**
2. Eric P. Brass-“Changing the status of drugs from prescription to over the counter availability”-New England J. Medicine, Vol: 345, No.11, Sept13, 2001.
3. Erin E. Baca, Juan Holguin Jr. and Andreas W. Stratemeyer, “Direct to consumer advertising and young consumers; building brand value”, The Journal of Consumer Marketing (2005); 379-387.
4. George S. Day and David B. Montgomery (1999), “Charting new directions for marketing”, Journal of Marketing, Vol.63 (Special Issue 1999), 3-13.
5. India 2020-A vision for the New Millennium –A.P.J. Abdul Kalam and Y.S. Rajan-1998 M.E. Porter and Mark R. Kramer -“Strategy and society”, HBR, Dec; 2006. M. Tolga Akcura, Fusun F. Gonul, Elina Petrova, “Consumer learning and brand valuation; an application on over-the-counter drugs”, Marketing Science, Vol: 23, No.1, Winter 2004, 156-169
6. Nirmalya Kumar- “Strategies to fight low-cost rivals”, HBR, Dec; 2006. Richard F. Beltramini-“Consumer believability of information in direct to consumer (DTC) advertising of prescription drugs”, Journal of Business Ethics (2006) 63; 333-343.
7. World health organization Mondiale de la Sante,” The role of pharmacist in health care system” Part-1, New Delhi, India,1988, Pg no-2,17,19,30. How to cite this article: S.V. Chordia, Role of pharmacist in rational drug therapy. J Surge Allied Sci 2019;1(Self-medication: awareness and attitude among undergraduate medical students in a tertiary care medical college, Dhule by Sandip Baharat Patel
8. Dickinson BD, Altman RD, Deitchman SD, Champion HC. Safety of over- the counter inhalers for asthma: Report of the council on scientific affairs. Chest. 2000;118(2):522- 6. Doi: 10.1378/chest.118.2.522, PMID 10936150.
9. Foley M, Breindahl T, Hindersson P, Deluca P, Kimergård A. Misuse of ’overthe- counter’ codeine analgesics: Does formulation play a role? Public Health. 2016; 130:95-6. Doi: 10.1016/j.puhe.2015.10.006, PMID 26612458. Benade D. Self-medication: A current challenge. J Basic Clin Pharm. 2013;5(1):19-23. Doi: 10.4103/0976-0105.128253, PMID 24808684
10. 11. Holloway K, Dijk VL. Rational Use of Medicines. World Medicines Situation Report. World Health Organization; 2011. Report No. WHO/EMP/MIE/2011.2.2. [accessed on October 9, 2015]. Ahttp://www.who.int/medicines/areas/policy/world\_medicines\_situation/W MS\_ch 14\_wRational.pdf.
11. Holloway K. Rational use of drugs: an overview. Technical briefing seminar. Department of Essential Medicines and Pharmaceutical Policy TBS 2009. Geneva: World Health Organization. Millar A (February 2018). "Defining OTC Drugs". Pharma Technology Focus (67). Retrieved 3 February 2018.
12. "Over-the-Counter Medicines: What's Right for You?" U.S. Food and Drug Administration (30 April 2009). Retrieved 4 July 2012.
13. "Understanding Over-the-Counter Medicines". Centre for Drug Evaluation and Research. U.S. Food and Drug Administration. 14 August 2019. Retrieved 26 August 2019.
14. "Prescription Drugs and Over-the-Counter (OTC) Drugs: Questions and Answers". Centre for Drug Evaluation and Research. U.S. Food and Drug Administration. 25 April 2019.
15. Saha A, Balakrishnan S, Trivedi N, Abraham GM (1 January 2023). "Hypertension and Severe Hypokalaemia Associated with Oral Ingestion of Topical Hydrocortisone Cream". AACE Clinical Case Reports. 9 (1): 2–4. Doi: 10.1016/j.aace.2022.10.004.
16. Mariam AH, Raghavendra Y, Bobasa. EM. Evaluating rational drug use with the help of World Health Organization’s core indicators in Bule Hora Hospital, Southern Ethiopia. Encounters. 2015;7(8):11.
17. Dilbato DD, Kuma ZG, Tekle-Mariam S. A baseline survey on prescribing indicators and the underlying factors influencing prescribing in Southern Ethiopia. Ethiop J Health Dev. 1998;12(2):87–94.
18. Yenet W. Baseline survey on drug prescribing indicators for outpatients in Jimma University Specialized Hospital, Southw est Ethiopia. Ethiop J Health Sci. 2005;15(2).
19. Hogerzeil HV, Ross-Degnan D, Laing R, et al. Field tests for rational drug use in twelve developing countries. Lancet. 1993;342(8884):1408–1410. doi:10.1016/0140-6736(93)92760-Q
20. Mahmood A, Elnour AA, Ali AAA, Hassan NA, Shehab A, Bhagavathula AS. Evaluation of rational use of medicines (RUM) in four government hospitals in UAE. Saudi Pharm J. 2016;24(2):189–196. Doi:10. 1016/j.jsps.2015.03.003 Kebodeaux CD. Prescription and over-the-counter medication record integration: A holistic patient- centered approach. J Am Pharm Assoc. 2019;59: S13–7. [PubMed]
21. Sansgiry SS, Bhansali AH, Bapat SS, Xu Q. Abuse of over-the-counter medicines: A pharmacist's perspective. Integer Pharm Res Pract. 2016; 6:1–6. [PMC free article] [PubMed] [Google Scholar]
22. Thomas L, Jayakrishnan SS, Joseph S, Varghese N, Dileep C, Rasheed A. Assessment of OTC drug labels for patient information in community pharmacies in Thiruvananthapuram city. Int J Innov Pharm Sci Res. 2014; 2:1034–41. [Google Scholar]
23. Wiley Handbook of Current and Emerging Drug Therapies. New Jersey: Wiley- Interscience; 2007. [Google Scholar]
24. Non-Steroidal Anti-Inflammatory Medicines. Cleveland Clinic [Internet] 2016. [Last cited on 2019 Jun 05]. Available from: https://my.clevelandclinic.org/health/drugs/11086-non-steroidal-anti-inflammatory- medicines-nsaids .
25. Ibuprofen in adults. Health Navigator New Zealand [Internet] 2019. [Last cited on 2019 Jun 10]. Available from: https://www.healthnavigator.org.nz/medicines/i/ibuprofen/Drug Applications for Over-the-Counter (OTC) Drugs. Fda.gov (2015-01-07). Retrieved on 2019-08-26.
26. "Drug Applications for Over-the-Counter (OTC) Drugs". Centre for Drug Evaluation and Research. U.S. Food and Drug Administration. 29 May 2019. Retrieved 26 August 2019.