

Over the counter drugs: Growth, benefits and side effects, RX to OTC switch process, classification, pharmacist role

Pooja pagare^{*1}, Sonali Tambe^{*2}, Rajeshree Muke^{*3}, Rutika More^{*4}, Dr. Rupali R. Tasgaonkar^{*5}

^{*1}Student, Yadavrao Tasgaonkar Institute Of Pharmacy Bhivpuri Road Karjat, India.

^{*2}Assistant Professor, Yadavrao Tasgaonkar Institute Of Pharmacy Bhivpuri Road Karjat, India.

^{*3,4}Student, Yadavrao Tasgaonkar Institute Of Pharmacy Bhivpuri Road Karjat, India.

^{*5}Principal & Professor, Yadavrao Tasgaonkar Institute Of Pharmacy Bhivpuri Road Karjat, India.

Corresponding author: Pooja pagare

Abstract—Over-the-counter (OTC) drugs are medicines you can buy without a doctor's prescription. People often use them to treat small health problems like headaches, muscle pain, colds, and allergies. This review explains what OTC drugs are, their advantages, and their risks. It also looks at how some medicines move from being prescription-only to OTC, with examples from India and the USA.

OTC drugs save money and time, and they reduce pressure on hospitals and doctors so they can focus on serious illnesses. But if people use them wrongly—such as taking the wrong dose, misusing them, or not knowing enough about them—there can be problems like side effects, drug resistance, or harmful interactions.

The review highlights the need for public awareness and proper guidance to make sure OTC drugs are used safely. Pharmacists play an important role in preventing misuse by counseling patients and spreading awareness. They can also limit supply or mark products as unavailable when needed to stop abuse.

Keywords—OTC drugs, self-medication, switching process, side effects, benefits, public health, pharmacists' role, drug safety.

I. INTRODUCTION

Over-the-counter (OTC) drugs are medicines that people can buy without a doctor's prescription. They are not listed as prescription drugs and are easily available in pharmacies and stores. According to the FDA, OTC drugs are "medicines that do not require a doctor's prescription and can be bought directly from stores." The National Institute on Drug Abuse (NIDA) also defines them as medicines that can be sold directly to people without a prescription.

OTC drugs are considered safe and effective when used correctly, and they are mainly used for self-medication. Self-medication can be helpful for patients, healthcare workers, governments, and pharmaceutical companies because it saves time, reduces costs, and makes treatment more convenient. However, if self-medication is not done properly, it can also cause harm.

Today, more people around the world prefer self-medication because it helps them manage minor health problems on their own. Easy access to information through social media and advertisements, along with the convenience of visiting a pharmacy instead of a hospital, has increased this trend. Common conditions treated with OTC drugs include colds, headaches, muscle pain, cramps, heartburn, and allergies.

OTC drugs are part of the modern healthcare system, which depends on consumer awareness, education, and social and economic factors.

There are two main types of OTC products:

- OTC medicines – sold only by registered pharmacists in pharmacies.

- OTC general products – sold in any outlet or store.

Improper use of OTC drugs can lead to problems such as allergies, hypersensitivity, and antibiotic resistance. Mistakes like not reading labels, ignoring expiry dates, taking double doses, or using expired products can cause serious side effects. In the past, drugs were often sold without prescriptions in bottles, sometimes containing harmful substances like cocaine, marijuana, or opium, with no information given to the user.

Over-the-Counter Medicine Examples



II. USE OF OVER THE COUNTER MEDICINES (OTC): SCENARIO ACROSS DIFFERENT COUNTRIES

- USA
 - OTC medicines are sold in pharmacies and supermarkets.
 - The FDA makes strict rules to keep them safe.
 - Labels are clear, and people get good information before use.
- India
 - OTC medicines are very easy to buy, even without a pharmacist.
 - Many people use them for cost-saving and convenience.
 - Misuse is common (wrong dose, antibiotics without advice).
 - Government is trying to improve rules and awareness.
- Europe (UK, Germany, France, etc.)
 - OTC medicines are sold mainly in pharmacies.
 - Pharmacists often guide patients before selling.
 - Antibiotics are not allowed as OTC to stop resistance.
- Developing Countries (Africa, parts of Asia)
 - OTC medicines are sold in shops and markets, often without guidance.
 - Misuse and expired drugs are common problems.
 - WHO suggests stricter rules and better education.

III. KEY POINTS

- OTC medicines help with small health problems like colds, headaches, and allergies.

- They save time and money but can be risky if misused.
- Countries with strict rules (like USA and Europe) have safer use.
- Countries with weak rules (like India and many developing nations) face more misuse.
- Pharmacists and public awareness are very important for safe use.

IV. GROWTH OF OTC DRUGS IN INDIA

India is one of the most populated countries in the world, and with such a huge population, visiting a doctor for every minor health issue can be a challenge. This has led to a steady rise in the use of over-the-counter (OTC) medicines.

Why people turn to OTC drugs

- Many people reuse old prescriptions without consulting a doctor again.
- Busy work schedules make patients avoid doctor visits to save time.
- Doctor consultations can be expensive, so people try cheaper alternatives.
- Some lack trust in doctors or medical professionals.
- Social advice and misbeliefs often push people toward self-medication.

V. BENEFITS OF OTC DRUGS

OTC medicines aren't just convenient — they also play a role in supporting society and healthcare systems.

- They help treat minor illnesses quickly and at low cost.
- Reduce the burden on hospitals and clinics, allowing doctors to focus on serious cases.
- Pharmacists can guide patients using their expertise.
- Improve public knowledge about managing small health problems.
- Encourage self-awareness and responsibility for personal health.

VI. SIDE EFFECTS OF OTC DRUGS

Despite their benefits, OTC drugs can cause problems if misused.

- Overuse can lead to drug resistance and complications.
- If they don't work, patients may end up spending more later.
- Misreading or ignoring instructions can cause harm.
- Risk of drug interactions and adverse reactions.
- Some OTC drugs can be addictive and misused.
- Wrong self-diagnosis may delay proper treatment.

VII. WHY SIDE EFFECTS HAPPEN

- Using the wrong medicine or treating symptoms incorrectly.
- Overusing or underusing drugs.
- Misuse and abuse due to easy availability.
- Poor or unclear labeling on packaging.
- Lack of awareness about safe usage.
- Taking multiple medicines (polypharmacy) without knowing the cause of illness.

VIII. PRESCRIPTION-TO-OTC SWITCH

Sometimes, drugs that were once available only by prescription are later approved as OTC. This process is called the Rx-to-OTC switch.

- Full Switch: The entire drug becomes available without prescription.
- Partial Switch: Only certain uses of the drug are OTC, while others remain prescription-only.

Before switching, regulators check:

1. The drug has high sales and consumer use.
2. It has been safely marketed for years.
3. Post-marketing data shows no serious side effects.

IN OTC Drugs in India

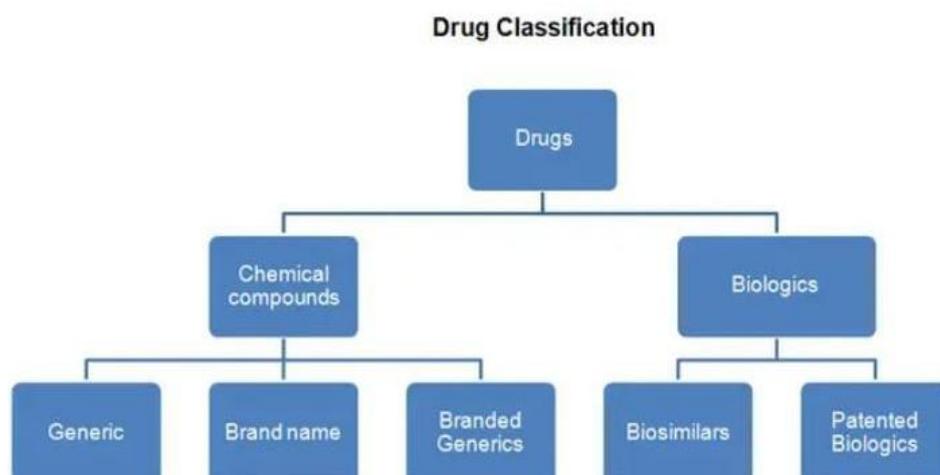
In India, the term "OTC" isn't officially defined under the Drugs and Cosmetics Act (1940) or Rules (1945). Still, pharmacists often sell these medicines without prescriptions.

Key drivers of OTC growth in India:

- Changing consumer attitudes toward self-medication.
- Product modifications and marketing.
- Pharmaceutical companies shifting focus from prescription to OTC drugs.

Categories of OTC products in India:

- True OTC products: Advertised openly and sold freely.
- Prescription drugs converted to OTC.
- Prescription drugs purchased OTC (without formal approval).



IX. ADVERTISING OF OTC MEDICINES IN INDIA

In India, there are strict rules about medicine advertisements. The Drugs and Magic Remedies Act says that companies cannot advertise cures for certain diseases, and they must not mislead people about what a medicine can really do.

The Drug Controller General of India (DCGI), along with the OPPI, has also made a voluntary code for how OTC (over-the-counter) medicines should be advertised.

Even with these rules, many OTC medicines are promoted on TV, social media, and other platforms. These include:

- Digestives and antacids
- Cold rubs, balms, and creams
- Vitamins, tonics, and herbal supplements
- Medicated skin treatments
- Painkillers and cold tablets
- Antiseptic creams and lotions
- Glucose powders
- Cough syrups and throat lozenges
- Baby gripe water
- Anti-acne creams
- NSAIDs (pain relievers)
- Smoking cessation products

X. COMMON TYPES OF OTC MEDICINES

OTC medicines are those you can buy without a doctor's prescription. Some common ones are:

- Pain relievers like paracetamol, aspirin, ibuprofen, and diclofenac. They help with fever, headaches, muscle pain, and arthritis. But they can cause side effects like liver damage (paracetamol) or stomach ulcers and bleeding (aspirin).
- Heartburn and indigestion medicines such as omeprazole or aluminium hydroxide. They reduce acid reflux and ulcers. Side effects can include headaches, nausea, vitamin deficiencies, or constipation.
- Laxatives like bisacodyl. These help with constipation and bowel preparation before medical tests. Overuse can cause cramps, diarrhea, dehydration, or imbalance of body salts.
- Anti-diarrheal medicines like loperamide. They slow down the intestines to reduce watery stools. Misuse can cause constipation, bloating, or even heart problems in overdose.
- Motion sickness medicines such as dimenhydrinate. They prevent nausea and vomiting during travel but may cause drowsiness or dry mouth.

- Nasal sprays/steroids like fluticasone. They help with allergies and nasal congestion but can sometimes cause nosebleeds or irritation.
- Cough medicines such as guaifenesin or dextromethorphan. They reduce coughing and clear mucus. Side effects include dizziness, stomach upset, and in cases of misuse, hallucinations.
- Antihistamines like cetirizine, loratadine, and fexofenadine. These are used for allergies and colds. They may cause drowsiness or dry mouth.

XI. ROLE OF PHARMACISTS

Pharmacists are often the first people patients talk to when buying OTC medicines. They:

- Help patients choose the right medicine.
- Explain how to use it safely.
- Prevent misuse or abuse of OTC drugs.

To stop abuse, pharmacists may:

- Refuse to sell certain products.
- Limit the quantity given.
- Require a prescription for risky medicines.
- Counsel patients about safe use.
- Raise awareness through campaigns and leaflets.
- Work with doctors or clinics to guide patients who misuse medicines.

XII. CONCLUSION

Over-the-counter (OTC) medicines are easy to access and very useful for treating common, minor health problems. Since they don't require a doctor's prescription, they provide a convenient and time-saving option for people who want to manage small issues on their own.

However, it's important for consumers to understand the basics of these medicines — such as their active ingredients, uses, possible side effects, and the risks of overdose or misuse. When taken correctly, OTC drugs are generally safe and effective. But if someone is unsure about their condition or how to use a medicine, they should seek advice from a healthcare professional.

Pharmacists play a key role here. They can guide patients, explain safe usage, and help prevent misuse or abuse. For example, one commonly misused drug is dextromethorphan, which can cause hallucinations if taken improperly. Pharmacists should counsel patients about such risks and encourage responsible use.

In short, OTC medicines are a helpful tool for self-care — but only when used wisely. People need proper knowledge before using them, and overuse should be avoided, especially among children, the elderly, or those with other health conditions.

REFERENCES

- [1] The Third National Health and Nutrition Examination Survey (NHANES III). *Pharmacoepidemiology and Therapeutics* 2003;12(4):315-326.
- [2] Mohammed. Self-medication - a serious threat to society. *LOJ Nursing and Health Care*. 2018, 1(1). DOI: 10.32474/LOJNHC.2018.01.000104.
- [3] Shaghghi A, Asadi M, Allahverdi H. Predictors of self-medication behavior: a systematic review. *Iranian Journal of Public Health*. 2014;43(2):136.
- [4] Abdullah IS, Chaw LL, Koh D, Hussain Z, Goh KW, Abdul Hamid AA, et al. Over-the-counter medicine attitudes and knowledge among university and college students in Brunei Darussalam: findings from the first national survey. *International Journal of Environmental Research and Public Health*. 2022;19(5):2658.
- [5] Bennadi D. Self-medication: a current challenge. *Journal of Basic and Clinical Pharmacy*. 2013;5(1):19-23. DOI: 24808684. 10.4103/0976-0105.128253.
- [6] Bekele KM, Abay AM, Mengistu KA, Atsbeha BW, Demeke CA, Belay WS, et al. Knowledge, attitude, and practice on over-the-counter drugs among pharmacy and medical students: A facility-based cross-sectional study. *Integrated Pharmacy Research and Practice*. 2020;9:135-146. DOI: 10.2147/IPRP.S266786. PMID: 32983946.
- [7] Nabors LA, Lehmkuhl HD, Parkins IS, Drury AM. Reading about over-the-counter medications. *Issues in Comprehensive Pediatric Nursing*. 2004;27(4):297-305. DOI: 10.1080/01460860490884192. PMID: 15764435.
- [8] Kebodeaux CD. Prescription and over-the-counter medication record integration: A holistic patient-centered approach. *J Am Pharm Assoc*. 2019;59:S13-7. doi: 10.1016/j.japh.2018.10.002.
- [9] Sansgiry SS, Bhansali AH, Bapat SS, Xu Q. Abuse of over-the-counter medicines: A pharmacist's perspective. *Integr Pharm Res Pract*. 2016;6:1-6. doi: 10.2147/IPRP.S103494.
- [10] 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
- [11] Wiley Handbook of Current and Emerging Drug Therapies. New Jersey: Wiley-Interscience; 2007.
- [12] Non-Steroidal Anti-Inflammatory Medicines. Cleveland Clinic [Internet] 2016. [Last cited on 2019 Jun 05].
- [13] Ibuprofen in adults. Health Navigator New Zealand [Internet] 2019. [Last cited on 2019 Jun 10].
- [14] Gupta S. Emerging Indian OTC markets. *AJMST*. 2013;1:24-9.
- [15] Statistics on OTC use. Consumer Health Products Association [Internet] 2019. [Last cited on 2019 May 21].
- [16] Chang J, Lizer A, Patel I, Bhatia D, Tan X, Balkrishnan R. Prescription to over-the-counter switches in the United States. *J Res Pharm Pract*. 2016;5:149-54. doi: 10.4103/2279-042X.185706.
- [17] Over-the-Counter (OTC) Drug Monograph Process. *Fda.gov* [Internet] 2015. [Last cited on 2019 Jun 11].
- [18] 11. Kartha S, Kulyadi G, Bhat K, Sathyanarayana M. Switching drugs from Rx to OTC status-A regulatory perspective. *J Young Pharm*. 2017;9:3-5.
- [19] Mahoney K. The ABCs of OTCs. Little Known Facts About Over The Counter Drugs. US Food and Drug Administration [Internet] [Last cited on 2019 May 28].
- [20] Generics/Non-prescription medicines- Non-prescription switching. European Medicines Agency [Internet] 2011. Jun, [Last cited on 2018 Feb 22].
- [21] Sood N, Sun E, Zhuo X. Behind-the-counter statins: A silver bullet for reducing costs and increasing access? *Health Serv Res*. 2012;47:174-87. doi: 10.1111/j.1475-6773.2011.01315.x.
- [22] Barrenberg E, Garbe E. From prescription-only (Rx) to over-the-counter (OTC) status in Germany 2006-2015: Pharmacological perspectives on regulatory decisions. *Eur J Clin Pharmacol*. 2017;73:901-10. doi: 10.1007/s00228-017-2240-4.

- [22] McKenney J, Brown W, Cohen J, Cahill E. The National Lipid Association surveys of consumers, physicians, and pharmacists regarding an over-the-counter statin in the United States: Is this a good idea? *Am J Cardiol.* 2004;94:16–21. doi: 10.1016/j.amjcard.2004.07.050.
- [23] ASHP statement on the over-the-counter availability of statins. *Am J Health Syst Pharm.* 2005;62:2420–2. doi: 10.2146/ajhp050342.
- [24] Hayashi M, Masuda S, Kimura H. Key information providers, channels, and characteristics of Japanese consumers' informed choices of over-the-counter medications. *Springerplus.* 2015;4:737. doi: 10.1186/s40064-015-1549-7.
- [25] Regulation of OTC drugs in Japan. Pharmaceuticals and Medical Devices Agency [Internet] 2014. [Last cited on 2018 Mar 02].
- [26] Emmerton L. The 'third class' of medications: Sales and purchasing behaviour are associated with pharmacist only and pharmacy medicine classifications in Australia. *J Am Pharm Assoc.* 2009;49:31–7. doi: 10.1331/JAPhA.2009.07117.
- [27] Advertising Therapeutic Goods. Therapeutic Goods Administration (TGA) [Internet] 2016. [Last cited on 2018 Jan 18].
- [28] White Paper: Status Quo of Drug Supervision in China. China FDA [Internet] 2008. [Last cited on 2019 Jun 10].
- [29] Ma F, Lou N. Regulation of drug promotion in China [Internet] 2013. [Last cited on 2019 Jul 11]. .
- [30] The Drugs and Cosmetics Act, 1940 and Rules, 1945 [Internet] [Last updated on 2016 Dec 31; Last cited on 2019 Jun 11].
- [31] India OTC Pharma Profile. Organisation of Pharmaceutical Producers of India [Internet] 2011. [Last cited 2019 May 21].
- [32] The Drug and Magic Remedies Act (Objectionable Advertisements Act), 1954 [Internet] [Last cited on 2019 Jun 9].
- [33] Chronicling a culture, celebrating a Bard [Internet] 2015. [Last cited on 2019 May 21].
- [34] Shet A, Sundaresan S, Forsberg BC. Pharmacy-based dispensing of antimicrobial agents without prescription in India: Appropriateness and cost burden in the private sector. *Antimicrob Resist Infect Control.* 2015;4:55. doi: 10.1186/s13756-015-0098-8.
- [35] Drug makers want free hand in pricing and advertising OTC drugs [Internet] 2018. [Last accessed on 2019 May 22].
- [36] Phalke VD, Phalke DB, Durgawale PM. Self-medication practices in rural Maharashtra. *Indian J Community Med.* 2006;31:34–5.
- [37] Dutta R, Raja D, Anuradha R, Dcruze L, Jain T, Sivaprakasam P. Self-medication practices versus health of the community. *Int J Community Med Public Health.* 2017;4:2757–61.
- [38] Kumar V, Mangal A, Yadav G, Raut D, Singh S. Prevalence and pattern of self-medication practices in an urban area of Delhi, India. *Med J DY Patil Vidyapeeth.* 2015;8:16–20.
- [39] Panda A, Pradhan S, Mohapatro G, Kshatri JS. Predictors of over-the-counter medication: A cross-sectional Indian study. *Perspect Clin Res.* 2017;8:79–84. doi: 10.4103/2229-3485.203043.
- [40] Jha D. 52% Indians self-medicate [Internet] 2015. Apr, [Last accessed on 2019 May 22]. Available from: .
- [41] Ravichandran A, Basavareddy A. Perception of pharmacists regarding over-the-counter medication: A survey. *Indian J Pharmacol.* 2016;48:729–32. doi: 10.4103/0253-7613.194857.
- [42] Shankar PR, Partha P, Shenoy N. Self-medication and non-doctor prescription practices in Pokhara valley, Western Nepal: A questionnaire-based study. *BMC Fam Pract.* 2002;3:17. doi: 10.1186/1471-2296-3-17.
- [43] Manohar HD, Manohar LH. Impact of knowledge and attitude on practices of over the counter medications. Proceedings of the 2015 International Conference on Operations Excellence and Service Engineering Orlando; September 10-11, 2015; Florida, USA. pp. 775–84.
- [44] Nagaraj M, Srinivas BN. A study on the dispensing pattern of over the counter drugs in retail pharmacies in Sarjapur area, East Bangalore. *J Clin Diagn Res.* 2015;9:11–3. doi: 10.7860/JCDR/2015/12940.6119.
- [45] Wazaify M, Shields E, Hughes CM, McElnay JC. Societal perspectives on over-the-counter (OTC) medicines. *Fam Pract.* 2005;22:170–6. doi: 10.1093/fampra/cmh723.
- [46] Cirstea SD, Moldovan-Teseliu C, Iancu AI. Analysis of factors that influence OTC purchasing behavior. In: Vlad S, Roman N, editors. International Conference on

- Advancements of Medicine and Health Care through Technology, 12th - 15th October 2016, Cluj-Napoca, Romania. IFMBE Proceedings. Vol. 59. 2017. pp. 303–4.
- [47] Marathe PA, Kamat SK, Tripathi RK, Raut SB, Khatri NP. Over-the-counter medicines: global perspective and Indian scenario. *Journal of Postgraduate Medicine*. 2020;66(1):28-34.
- [48] Sangeetha N, Shaguftha Ruhi B, Shashank Gowda S, Shobhitha CV, Srividya, Ravinandan AP, Ahmed SM. An educational review on over-the-counter drugs: a pharmacovigilance-based approach. *International Journal of Pharmaceutical and Chemical Analysis*. 2024;11(4):295-302.
- [49] Ferner RE, Beard K. Over-the-counter medicines: proceed with caution. *British Medical Journal*. 2008;336(7646):694-696. DOI: 18369225. 10.1136/bmj.39504.389676.AD. PMID: 18369225.
- [50] <https://www.fda.gov/drugs/drug-application-process-nonprescription-drugs/prescription-nonprescription-rx-otc-switches>.
- [51] Kartha S, Kulyadi G, Bhat K, Sathyanarayana M. Switching drugs from Rx to OTC status - a regulatory perspective. *Journal of Young Pharmacists*. 2020;9:3-7.
- [52] India Corporate Law. Over-the-counter drugs - regulatory clarity on the horizon. India: India Corporate Law; 2020.
- [53] Wire B. Global pet wearable market (2020 to 2025) - industry trends, share, size, growth, opportunity and forecast. 2020.
- [54] India's doctor-patient ratio still behind WHO prescribed 1:1,000: Government. *Business Standard*. 2021.
- [55] 17Pharma formulators diverge on strategy for non prescription businesses: Indra report. *Express Pharma*.
- [56] Raju KV. A comparative study of over-the-counter drug regulations in India and United States of America and European Union. *Asian Journal of Pharmaceutics*. 2023, 17(4). DOI: 10.22377/ajp.v17i04.5082.
- [57] Raja BM, Rao KR. Regulatory and clinical requirements for prescription to OTC switches in US and India.
- [58] Brass EP. Changing the status of drugs from prescription to over-the-counter availability. *New England Journal of Medicine*. 2001;345(11):810-816.
- [59] Gülpinar G, Özçelikay G. OTC drug regulations in Turkey: the opinions of community pharmacists and drug industry. *Turkish Journal of Pharmaceutical Sciences*. 2015;12(3):267-278.
- [60] Divya J. Over-the-counter (OTC) medicines.
- [61] American College of Gastroenterology. Acetaminophen toxicity and liver injury: a review. *The American Journal of Gastroenterology*. 2019;114(5):722-728.