

**ROLE AND IMPACT OF OVER-THE-COUNTER DRUGS IN EVERYDAY  
HEALTHCARE****Vinamer Sood<sup>1</sup>, Amiteshwar Singh<sup>1</sup>, Neeraj<sup>1</sup>, Navneet Sharma<sup>1</sup>, Daljeet Masih<sup>1\*</sup>**<sup>1</sup>University Institute of Pharma Science, Chandigarh University, Mohali, Punjab, India**ABSTRACT**

Over-the-counter (OTC) medications are pharmaceutical products available to consumers without a prescription, signifying a drug's favorable safety-toxicity profile for self-administration under recommended guidelines. The transition of drugs from prescription-only (Rx) to OTC status is a complex, multifactorial process influenced by advances in pharmacology, regulatory policies, and evolving public health priorities. Historically, medications were widely accessible until increasing awareness of health risks led to stricter regulations in the early 20th century. Modern reclassification from Rx to OTC status is predicated on robust post-marketing surveillance data that affirm safety, low abuse potential, and minimal adverse interactions.

Regulatory bodies such as the U.S. FDA and the European Medicines Agency (EMA) play pivotal roles in overseeing this process through stringent frameworks encompassing drug approval, labeling, and continuous safety monitoring. This regulatory oversight ensures that OTC medications maintain high standards of safety, quality, and efficacy, supporting their widespread use in self-care and public health strategies.

**Keywords:** Over-the-counter drugs, prescription to OTC switch, drug safety, FDA, EMA, regulatory framework, post-marketing surveillance, drug reclassification, self-medication, non-prescription medications.v

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## INTRODUCTION

Over-the-counter (OTC) medications are those that one can obtain without needing a doctor's prescription. These are drugs that are considered safe and are self-medicated due to their efficacy for individuals following the instructions given on the product labeling [1]. Being considered as a drug is OTC and the only reason for this is the safety-toxicity balance, primarily the safety of the drug in proportion to the risks of having non-communicable diseases.

The passage of OTC medicines from prescription-only (Rx) to the current situation of free market is a long-convoluted road, which has crashed through various stages and due to various factors. Moreover, the above-mentioned process entails the progress in the pharmacy branch, legislative policies, and national health systems. Back in the day, several medications were sold freely until the turn of the 20th century when the health risks and drug efficiency issues conceived the need for regulations [2]. Generally, the resulting transition from Rx to OTC status means that the drug should first be checked with respect to its safety, including the adverse effect rates, drug interactions, and the likelihood of misuse. This kind of re-evaluation is usually done through finding additional post-marketing data that are simply by their nature and clearer than data from clinical trials regarding safety and efficacy [3]. To illustrate this, some particular antihistamines and proton pump inhibitors (PPIs) were moved from recipes to OTC based on a safety profile that implied a low likelihood of adverse effects with correct use [4]. This change is a certain classification of pharmaceuticals, which is the best example of the reclassification based on new scientific knowledge and changing public health needs.

The safety and quality of OTC drugs would not rise to these high levels if not for the role played by the regulatory framework. The cornerstones here are the standards for the drug's approval, labeling, manufacturing, and post-marketing surveillance. The primary aim is to ensure the safety of consumers through the soundness of the OTC drugs that are to be taken by consumers at their will [5].

In the United States, the Food and Drug Administration (FDA) is the primary government regulatory entity that is responsible for the monitoring of OTC drugs. The FDA publishes the monographs that spell out the rules which contain the ingredients, doses, and other details that different category of OTC drugs is permitted to utilize. In Europe, the European Medicines Agency (EMA) and national regulatory authorities jointly accomplish the task of guaranteeing the safety and efficacy of over-the-counter medicines. These agencies employ a risk-based strategy which sums up the potential toxicities, possible misuse, and the impacts on the community [6].

### **Global Market Overview of OTC Pharmaceuticals**

The OTC pharmaceutical market has experienced an underlined increase, which has been fueled by

a series of foundational trends. Alleviating the market of the healthcare burden through self-medication is one aspect of this change, which is being driven by the affordability of healthcare, ease of learning, and the power of digital channels [7]. The OTC market is, therefore, a large contributing component of the global pharmaceutical industry, which speaks to its wealth. Breaking new grounds, such as advanced formulations and delivery systems, not to mention adding the variety of OTC categories, the market still grows ripe for new innovation [8].

There are considerable regional differences in the availability and usage of OTC medications. Regulatory frameworks, cultural practices, and socioeconomic factors are often the major culprits for this inequality across nations. Developed areas such as North America and Europe are easily recognizable as the regions where OTC markets are mature with a plethora of products that are readily available, and well-functioning regulatory systems [10]. People living in these places usually get extensive information which makes their health literacy a high standard. All these factors have a direct effect on the way self-medication is practiced.

### **Transition from Prescription to OTC Status**

The movement from Rx to OTC status is about the thorough assessment of the safety profile of the drug and the potential of drug abuse. The responsible regulatory authorities like the FDA in the U.S. and the EMA in Europe lay down the necessary specific criteria for this switch. The most critical selection is safety which has to be proven well before anything else; the second must be a low risk, and the last one a clear labeling which is needed for the consumers to self-diagnose and self-treat the condition successfully [13].

The course of events often is the provision of huge data that display the drug's safety and efficacy in a self-selection and self-plus-plus-use environment. Such data may include clinical trials, studies on consumer behavior, and data from post-marketing surveillance. The risk agency has to retain a record of the potential adverse effects, drug interactions, and the right of the consumers to comprehend the labeling and comply with it precisely. The labeling must provide a clear and unambiguous explanation of the intended use, dosage, precautions, and potential risks of the drug [14].

Some of the transitions are Rx-to-OTC proton-pump inhibitors omeprazole (Prilosec OTC) contained proton-pump inhibitors, which moved from Rx to OTC in 2003. This transition was made possible by all the safety data that were available, the consumer education and the regulatory evaluations that were conducted in order to ensure this proper self-use [22].

The well-known example is the switch of proton pump inhibitors (PPIs) like omeprazole (Prilosec OTC), which received approval for OTC use from the U.S. Food and Drug Administration (FDA) in 2003. The decision was based on data collected through a wide range of clinical studies that

confirmed the effectiveness and safety of the medication for frequent heartburn. The switch not only allowed patients to use a new treatment, but it also contributed to a decrease in the number of doctor visits needed for the treatment of mild-to-moderate gastroesophageal reflux disease (GERD). [16]. A different one has gone the route of loratadine (Claritin), the second generation antihistamine that received FDA OTC approval in 2002. With the safety profile already established, loratadine was an allergy medication widely available to patients who wanted to stay away from first-generation antihistamines that caused more sedation. The change has enabled people to deal with seasonal allergic rhinitis by themselves, thus decreasing the need for doctors to prescribe alternatives [17].

### **Regulatory System and Governance**

The World Health Organization (WHO) is an organization that is of tremendous importance in setting the international standards for pharmaceutical products, including OTC medications. The WHO guidelines are driven by the intent to promote the rational use of medicines & accompany a certificate that patients have safe and effective choices available to them at all times. These guidelines encompass various areas of OTC drug regulation, such as ensuring quality, labeling, and risk management [19].

The execution of harmonization at the global scale is a major step toward the objectives of regulatory conformity and the assurance of OTC medication standardization. These efforts are directed towards reducing the non-tariff barriers, fostering the trade and thereby improving the access of self-care options which are both safe and effective. Entities such as ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) are among the main players involved in the harmonization [21].

### **National Regulatory Bodies and Their Role**

#### **i. FDA, EMA, CDSCO, and Other Key Regulatory Authorities**

As illustrated in Table 1, the Food and Drug Administration (FDA) in America, the European Medicines Agency (EMA) in Europe, and the Central Drugs Standard Control Organization (CDSCO) in India are the top organizations dealing with regulation. Each of these agencies is guided by a specific legal and administrative framework that is in accordance with their national or regional context. The FDA, functioning under the Federal Food, Drug, and Cosmetic Act, implements a full-scale regulatory approach, including the New Drug Application (NDA) process and the OTC Monograph System in the introduction. The OTC Monograph System that the FDA has developed helps to speed up the process of drug approval by establishing a list of ingredients and labeling requirements. The FDA's responsibilities go beyond correctness for OTC drugs, as the agency's goal is to ensure the products are safe, effective, quality and the labeling accurately depicts this as reflected in the Drug Facts Labeling requirements [25].

## ii. Approval Processes and Post-Marketing Surveillance

The surveillance activities which are carried out by the national regulatory bodies after the approval processes are essential for the continuous safety and efficacy of OTC medications. The OTC medication approval process is a lengthy one with arduous tasks of checking the design, safety, and efficacy through clinical trials and consumer behavior studies. According to the Table 1, the FDA follows the NDA process while the EMA employs the MAA process that the CDSCO also follows the NDA procedure along with specific OTC drug approval requirements. [28].

### Labeling Requirements and Consumer Information

Package inserts, also known as patient info leaflets, are crucial OTC drug labeling. Regulatory agencies put in place strict rules on the content and format of these inserts so that consumers get the information they need to be accurate and understandable. These standards aim to minimize the risk of medication errors and adverse drug reactions [31].

In USA, the Food and Drug Administration (FDA) stipulates that package inserts shall carry information on the active ingredients of the drug, indications for its use, required dosage, method of administration, contraindications, and warnings about possible adverse effects. Moreover, the FDA mandates that the language used in package inserts be clear and concise, again, technical terms that are hard to understand for the consumer should be avoided [32].

Likewise, the EMA provides guidelines on the content and format of patient information leaflets, emphasizing the importance of clear language. The EMA also requires that package leaflets include information on the drug's interactions with other medications and the special risks to the population, to be pregnant women and children [33].

Consumer-friendly labeling approaches are crucial for enhancing the readability and comprehensibility of OTC drug information. These techniques present information in a clear, concise, and accessible manner, seeking to cater the needs of diverse consumer populations who have different levels of health literacy [34].

Evaluating the readability of labeling is a tool for assessing the success of information. This is benchmarking the extent to which the consumer understands the information and can make inferences. Readability tests are common tools such as the Flesch-Kincaid readability test and the Simple Measure of Gobbledygook (SMOG) index in practice [35].

### Pharmacology and Therapeutic Categories of Common OTC Drugs

#### Analgesics and Antipyretics

Nonsteroidal anti-inflammatory drugs (NSAIDs) are analgesic and antipyretics belonging to the class of drugs that are mostly acting by the inhibition of cyclooxygenase (COX-1) enzymes. This action is shown in the Mechanism of Action Diagram. By this inhibition, the synthesis of

prostaglandins, which are mediators of pain, inflammation, and fever, is reduced. NSAIDs are the first choice of drugs for relieving mild and moderate pain, such as headache, muscle aches, menstrual cramps, and arthritis. They are beneficial for lowering fever, as well. Ibuprofen is a good example of a drug, which is most often used for pain relief and fever reduction. Also, aspirin is used because of its antiplatelet effect in cardiovascular disease prevention [37].

Acetaminophen is also known as a paracetamol, which is a widely consumed OTC analgesic and antipyretic. The chemical structure of acetaminophen is depicted above, while its comparative properties can be found in Table 2. Acetaminophen is different from NSAIDs as it does not show significant anti-inflammatory activity. The mechanism of action for this drug involves COX enzyme blocking in the CNS, which results in a decreased amount of prostaglandin in the brain and spinal cord [38]. Even though the exact mechanism is not yet known, it is thought to engage in the modulation of the endocannabinoid system and the serotonergic pathway. Both conditions contribute prominently to the development of headaches. Acetaminophen is indicated for the relief of mild to moderate pain and fever, including headache, muscle aches, and toothache. It is usually very well-tolerated, having a substantially lower incidence of GI adverse effects in comparison to NSAIDs. On the contrary, it has a hepatotoxic risk, especially in the case of overdose or in patients who have liver disease [39].

### **Cough, Cold, and Allergy Products**

Antihistamines are a group of medications that prevent the effects of histamine in the body by binding them H1 receptors, just like in the Mechanism of Action Diagram. The action maintains histamine-caused effects, such as vasodilation, raised vascular permeability, and smooth muscle contraction, which are being responsible for the allergy symptoms [43].

First-generation antihistamines, e.g., diphenhydramine and chlorpheniramine, are noted for their central nervous system (CNS) effects such as sedation and cognitive impairment. Their ability to penetrate through the blood-brain barrier was the main reason for this effect. Are these unique structures that are responsible for the lipophilicity of the drugs? Most of them have a chemical structure that was often preserved that way and that helps them to be coincident with blood-brain barrier and other water soluble structures. The fact that these drugs are effective in eliminating allergy symptoms but are also accompanied by significant drowsiness makes them inappropriate for alertness-related activities. Second-generation antihistamines, e.g., cetirizine and loratadine, were specifically designed to avoid CNS effects with the goal of achieving sedative activity. The alteration in their chemical structure makes it sufficient for them to increase the polarity and decrease the lipophilicity, which in turn reduces the bloodbrain barrier's crossing ability. These medications are effective for treating allergies and have minimal sedation side effects, which makes

them suitable for daytime use [44].

### **Gastrointestinal Medications**

The OTC antacids, H<sub>2</sub>-receptor antagonists, and proton pump inhibitors (PPIs) are often consumed medications for the treatment of heartburn and indigestion. Antacids such as calcium carbonate and magnesium hydroxide neutralize stomach acid resulting in immediate but short-term relief. H<sub>2</sub>-receptor antagonists like ranitidine and famotidine work by blocking H<sub>2</sub> receptors on the parietal cells, therefore, decreasing gastric acid secretion [49]. . The choice between these medications is based on the severity and frequency of the symptoms. Antacids should be used for infrequent heartburn, while H<sub>2</sub>-receptor antagonists and PPIs are more effective in cases of frequent or chronic symptoms. PPIs are preferable in terms of a strong and long-lasting acid-suppressing effect [50].

Laxatives and antidiarrheals are a common list of OTC medications for the treatment of diarrhea. Laxatives like psyllium increase stool volume which, as a result, will cause peristalsis. Osmotic laxatives, e.g., polyethylene glycol lead to water influx into the colon, which results in soft stool. A stimulant laxative, such as bisacodyl, stimulates the intestinal peristalsis to expel the stool from the body. Stool softeners, like docusate, help to reduce the surface tension in the stool, which is usually caused by the mixing of water and fat [51]. The patient education on proper use and all possible side effects are important in treating constipation and diarrhea. Laxatives should be used in caution with patients who have abdominal pain or intestinal obstruction. E.g. Antidiarrheals are not to be used in cases of diarrhea accompanied by blood or fever [52].

### **4. Conclusion**

The evolution of OTC medications from prescription-based status underscores the critical balance between accessibility and safety. Reclassification is not arbitrary but depends on rigorous evaluation of post-marketing data and regulatory oversight to protect public health. National and international regulatory agencies have developed comprehensive systems that ensure OTC drugs meet strict safety, labeling, and efficacy standards. The role of these agencies is vital in maintaining public trust and safeguarding self-medication practices. As scientific knowledge and healthcare systems advance, the dynamic reclassification of drugs will continue to align with the goals of improving healthcare accessibility while minimizing risks to

consumers.

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