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Review Article

Navigating the Landscape of OTC Drug Utilization and Regulatory Challenges in India: Insights Review

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ABSTRACT

This review article on utilization and regulations of OTC drugs aims to highlight the significance of establishing legal policies on "OTC medicines" in India by outlining the potentially harmful effects of these medications on specific populations. The paper outlines OTC drug utilization and regulation in India, highlighting the need for a formal OTC drug category to establish a clear legal distinction between OTC and prescription drugs, enhancing regulatory clarity and market transparency. Strengthening pharmacovigilance is crucial for monitoring adverse events and drug interactions, while stricter controls are necessary to prevent counterfeit drugs. Regulating e-commerce and online pharmacies is also essential to ensuring the quality and safety of online drugs. Public education campaigns on safe self-medication are recommended to promote responsible usage and reduce adverse effects. A well-regulated OTC market can stimulate industry growth and innovation, allowing companies to develop new products while maintaining safety standards. Harmonising India's OTC regulations with international standards will benefit both the domestic market and export potential, ensuring that Indian OTC drugs align with global safety and quality practices. India's OTC drug regulation is confusing due to the lack of formal classification, unclear guidelines for online sales, and inconsistent labeling standards. The growing e-commerce sector increases access, but lack of clear regulations poses risks of counterfeit products and unauthorised sales. Collaboration between regulators, the pharmaceutical industry, and consumers is crucial for promoting safe self-medication practices.

Keywords: Drug, Market, Over the Counter (OTC), Pharmaceutical, Policies, Regulation.

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INTRODUCTION

Pharmacists legally sell OTC (Over-the-Counter) medicines without a prescription, and they are commonly used for minor ailments. Major contributors to OTC sales include the USA, Japan, Germany, and the UK. Countries have established varying guidelines for classification, regulation, and usage. USA: extensive classification with more than 80 classes of OTC medicines. European Union (EU): Non-prescription medicines are divided into pharmacy and general sales medicines. Japan: OTC medicines are categorized into different risk levels. Australia: divided into pharmacy medications, pharmacist-only. In India, there are no specific guidelines for licensing or categorizing OTC medicines, and the term is used more for practical application than official classification. Medicines not listed under prescription drug schedules (H, H1, and X) are generally sold as OTC and lack legal recognition. No doubt, OTC medicines offer greater access to treatment at lower costs and reduce healthcare burdens. However, misuse can lead to adverse health effects and risks related to patient safety. Recommendations include developing policies for drug classification, labelling, licensing, distribution, and pricing (Marathe *et al.*, 2020).

India reveals a lack of specific guidelines and a standardized process for transitioning from prescription-only to OTC status. This lack of regulations increases the risk of misuse, overuse, and inappropriate self-medication, leading to potential adverse health effects, drug resistance, and dependence. Limited oversight of advertising and promotion can also lead to misleading information and improper use. The review paper advocates for the establishment of a formal regulatory framework for OTC medicines and guidelines. Patient education and pharmacist involvement are crucial for safe OTC drug use, enabling informed choices and clear labeling from pharmaceutical companies.

The public's perception of OTC drugs as safer than prescription drugs is skewed, with studies showing potential harmful effects due to inappropriate use. Commonly abused classes include codeine cough syrups, antihistamines, sedatives, laxatives, and decongestants. Ensuring safety, effectiveness, and rational

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use is crucial for public health. Regulations should cover drug classification, licensing, labeling, distribution, advertising, pharmacovigilance, post-market surveillance, consumer education, clear instructions, warnings, contraindications, and market surveillance. Regulations should also involve healthcare professionals in guiding and educating patients. The scope of OTC drug regulation includes defining which drugs can be classified as OTC, establishing a regulatory process for approval, ensuring comprehensive labeling, and implementing post-market surveillance systems (Cooper 2013 and Rautio *et al.*, 2020).

Overview of OTC Drugs

The term OTC is not well defined under the Drug and Cosmetic Act 1940 and the Drug and Cosmetic Act 1945. For a drug to be OTC, it should be marketed as a prescription drug for at least 5 years or according to the rules of the WHO. Recently, in the country, the Druggist Association has opposed the plan of the Government to sell OTC without a pharmacist license, which will contravene the existing rules and regulations of the Pharmacy. Dispensing Over-the-Counter (OTC) medicines without appropriate monitoring and in the absence of a pharmacist may hinder adherence to proper usage guidelines, posing a significant risk to consumers (Meghana *et al.*, 2021).

OTC drug sales are increasing in India, showing that the nation's pharmaceutical sector is growing quickly. The Indian OTC medicine market is expected to rise from its 2022 valuation of USD 7.62 billion to USD 18.49 billion by 2027. The second-largest export from India to the US is OTC and prescription drugs. The COVID-19 epidemic had a significant impact on the market. The concept of OTC drugs is starting to gain in urban India because of increased health consciousness, high levels of working stress, and technological advancements and advertisements. The epidemic of 2020 brought changes to the healthcare system of India. Access to healthcare including online consultations with physicians and the self-medicating behaviour of the Indian population tremendously peaked with the pandemic 2020. There have been considerable changes in the attitudes and approaches of the Indian population to OTC drugs and self-medication behavior. Digital platforms such as social networks and health-related applications have contributed to a rise in the public's knowledge about OTC medications and self-medication. The balance of the Indian healthcare system is disturbed due to shifting disease patterns, a smaller number of physicians, uneven health services across the rural and urban population, and out-of-pocket expenses.

Non- prescription drugs

OTC drugs are safe, effective medications available for public use without a healthcare provider's prescription. Common categories of OTC drugs include pain relievers, cold and allergy medications, digestive aids, cough suppressants and expectorants, topical medications, sleep aids, weight loss aids, vitamins and supplements, and supplements. Safety considerations for OTC drugs include always reading and following the instructions on the label, being aware of potential interactions with other medications, consulting a healthcare provider if you have any underlying health conditions, are pregnant, or are nursing, and keeping them out of reach of children. It has a significant impact on the healthcare system in various ways, such as increased accessibility to healthcare, reduced healthcare burden, ease of access, support for public health initiatives, economic impact, potential risks and challenges, regulatory and safety concerns, role in chronic disease management, impact on prescription drug demand, and healthcare system integration. Consequences of OTC drugs include convenience and accessibility, cost savings, reduced absenteeism from work or school, empowerment in self-care, immediate action, chronic disease management, and support for healthy lifestyles. However, there are also potential risks related to misuse, safety, and delayed professional care that need to be managed through proper regulation, education, and integration with professional healthcare services (FDA 2021, WHO 1998, and NIH 2025).

Prescription (Rx) to OTC switch

It is the transfer or switch of a prescription drug to an OTC product. Common reasons for switching from Rx drugs to OTC drugs are economic considerations, time-saving, an increase in population, self-medication, easy availability, and to enhance the corporate revenue from the manufacturer's view. The process of transitioning prescription drugs to OTC status is intricate and involves collaboration between the industry, regulatory authorities, and healthcare professionals. In certain cases, products have reverted from OTC back to prescription status due to safety issues. Many countries use the WHO Anatomical Therapeutic and Chemical classification system as their approved list for OTC medicines (Mead 2005, FDA 2011, and Harrington *et al.*, 2002).

Basic Criteria for Switching Rx to OTC

- Consistent symptom relief
- Broad safety margin
- Lower potential risks compared to prescription drugs
- Fewer adverse drug reactions or side effects
- Unchanged pharmacokinetic effects
- Low risk of dependence or abuse
- The same active ingredients available as OTC in a different dosage form, marketed as a prescription drug for at least 5 years

Historical context and evolution of OTC drug use in India

The histogram visually represents the growth and significance of the Indian pharmaceutical sector and the availability of OTC drugs across different periods (Figure 1). Each bar corresponds to a key historical phase, with the height of the bar indicating the relative impact or significance during that period (Chaudhuri 2005, Basu 2006, Jadhav *et al.*, 2016, Mishra *et al.*, 2010, and Saraswathy 2006).

Timeline Data Points

1. Early 20th Century

   a. **Event:** Traditional Medicine Dominance.

   b. **Description:** Widespread use of Ayurveda, Unani, and Siddha, with limited access to Western medicine.

2. 1940

   a. **Event:** Introduction of the Drugs and Cosmetics Act.

   b. **Description:** The act begins to regulate the sale of medicines, laying the groundwork for the future classification of OTC drugs.

3. Post-Independence (1947 onwards)

   a. **Event:** Growth of the Indian Pharmaceutical Industry.

   b. **Description:** Establishment of public sector units to manufacture affordable and accessible drugs.

4. 1960s-1970s

   a. **Event:** Emergence of OTC Drugs.

   b. **Description:** Pharmaceutical companies introduce pain relievers, cold medications, and antacids that can be purchased without a prescription.

5. 1990s

   a. **Event:** Market Expansion and Economic Liberalization.

   b. **Description:** The Indian economy opens up, leading to rapid growth in the pharmaceutical sector and increased availability of OTC drugs.

6. 2000s to Present

   a. **Event:** Digital Revolution and Regulatory Changes.

   b. **Description:** Online pharmacies are emerging, and regulations for Over-the-counter (OTC) drugs are continuously evolving to ensure consumer safety.

7. Present

   a. **Event:** Public Health Concerns.

   b. **Description:** The increasing awareness of the risks of misuse and antibiotic resistance has prompted discussions on stricter regulation.

OTC drug use in India has evolved due to the country's cultural, social, and economic landscape. Traditional medicine systems, Western medicine, and the Drugs and Cosmetics Act of 1940 regulated the sale of OTC drugs. The liberalization of the economy in the 1990s led to rapid growth in the pharmaceutical sector. Regulatory changes have been made to clarify OTC drug regulations and ensure consumer safety. The digital revolution has transformed OTC drug marketing and sales, making them more accessible, even in remote areas. However, concerns about misuse, overuse, and antibiotic resistance have grown, leading to debates about stricter regulation and consumer education.

A global perspective on OTC drug utilization

The global OTC market is dominated by the USA, Japan, Germany, and the UK, with distinctions between OTC and prescription medicines. WHO criteria for OTC include at least five years without serious adverse reactions. In the USA, drugs must meet the benefits-risk ratio, low misuse potential, consumer awareness, and labeling requirements. The US FDA uses "OTC monographs" for regulation; drugs outside these monographs require New Drug Application (NDA) approval. Common OTC categories in the USA include antacids, antidiarrheal products, antiemetics, and analgesics. Challenges include balancing self-treatment benefits with misuse risks and Issues can arise due to cultural differences within unions like the EU, which comprises 27 countries. Stakeholder involvement and industry cooperation are crucial for improving the drug approval process.

Current Utilization Trends in India

OTC medications are not covered under the D&C Act of 1940, as per Indian legislation. The CDSCO plans to create a robust, policy-supporting regulatory framework for OTC drugs. The government and several pharmaceutical companies are spearheading multiple initiatives to raise awareness about different drugs and switch prescriptions to OTC products. In India, to date, there are no specific regulations for the switching of prescription to OTC drugs. Based on the recommendations by the Ahooja Committee in 2022, rules have been approved by the Drugs Consultative Committee (DCC) for the drafts containing 16 drugs, which consist of antifungals, laxatives, antihistamines, and decongestants. This regulation, which was put out by the Ministry of Health and Family Welfare of India, can be a basis for new OTC policies in the country (Narang *et al.*, 2023).

India needs to recognize OTC medicines as a separate category due to their rampant misuse. Necessitating strict rules and clear labeling norms need to be emphasized. The Drugs Consultative

Committee recommends creating a separate category for OTC drugs, with a subcommittee examining various schedules and conditions for marketing certain drugs as OTC, enhancing patient education through national campaigns, and implementing prescription monitoring programs. Increased public awareness and clear labelling are also crucial. Strengthening adverse effect reporting systems and involving stakeholders is essential for rationalizing OTC medicine use in India.

Commonly used OTC drugs in India

The National Medical Commission (NMC) has issued regulations allowing over-the-counter dispensing of various therapeutic categories of drugs, including anti-hemorrhoid drugs, topical antibiotics, cough-suppressants, anti-acne drugs, non-steroidal anti-inflammatory medicines, decongestants, aspirin, vasodilators, antacids, expectorants, anti-fungal drugs, antihistamines, anti-flatulence agents, and smoking cessation drugs. This lack of specific drug names may lead to the misuse of habit-forming drugs. Additionally, self-medication with some of these drugs may lead to toxicity. In India, due to different reasons, individuals depend on OTC medications and practice self-medication. This may lead to numerous issues, as a few symptoms can be warning signs of dangerous disease conditions. For instance, even though most headaches are not dangerous, they can be a symptom of a brain tumor or stroke. Similarly, heartburn can be an indication of gastric-related issues or angina (Ahmed *et al.*, 2022). Histogram showing the hypothetical frequency of different factors influencing OTC drug utilization (Fugure 2).

The factors are listed on the y-axis, with the frequency on the x-axis. The histogram highlights the relative importance of each factor based on the assumed frequency data. Efficacy of OTC products and following the previous prescription are among the most influential factors. Advertisements, Cost-effectiveness, and Lack of time also play significant roles. Misbeliefs and Less trust in doctors have a lower frequency but still contribute to OTC drug utilization.

Image displaying the Odds Ratios (OR) with 95% Confidence Intervals (CI) for various predictors related to OTC medication use (Figure 3). Each bar represents a predictor, with the length of the bar indicating the odds ratio, and the error bars representing the confidence intervals. The red dashed line at OR = 1 indicates no effect. A good lifestyle has the highest odds ratio, indicating a strong association with OTC use. Male gender and higher income also show a significant positive association. Living with family, having completed school, and age over 45 show a lower odds ratio, indicating a lesser likelihood of OTC use compared to their counterparts (Panda *et al.*, 2017).

Regulatory Framework in India

Overview of the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945. The Drugs and Cosmetics Act of 1940 regulates the import, manufacture, distribution, and sale of drugs and cosmetics, ensuring safety, quality, and accurate consumer information. The Rules of 1945 provide detailed implementation guidelines. They cover various aspects such as the licensing

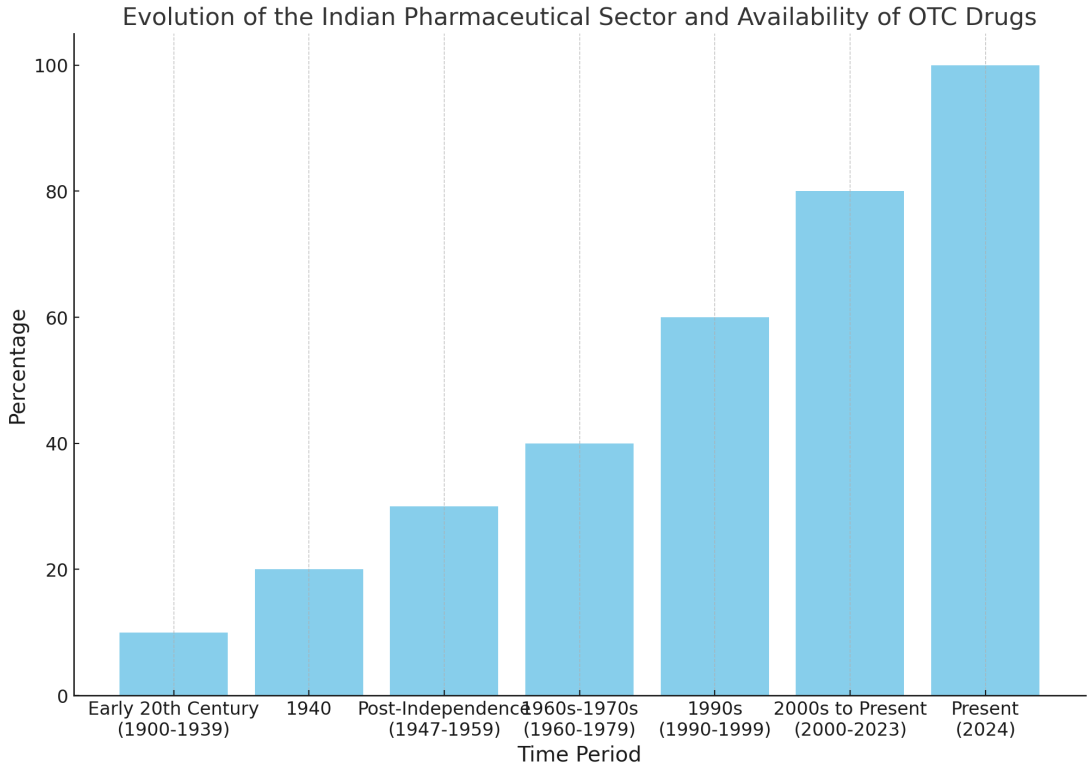

Figure 1: Historical context and evolution of OTC drug use in India.

requirements for manufacturing drugs and cosmetics, production standards, quality control measures, and labelling.

Role of the Central Drugs Standard Control Organization (CDSCO)

CDSCO, India's National Regulatory Authority, oversees drug approval, clinical trials, sets standards, controls imported drugs, and coordinates with State Drug Control Organizations to ensure patient safety. OTC drugs are safe, effective self-medication medications that can be purchased without a prescription. The Drugs and Cosmetics Act of 1940 regulates these drugs in India, while the Drugs and Cosmetics Rules, 1945, provide guidelines. Licensing and approval require licenses from the CDSCO or state drug controllers and evidence of safety and efficacy. Labels must include information about the drug's name, ingredients, dosage instructions, side effects, and warnings. Non-compliance may result in fines, license suspensions, or product recalls. Amendments focus on modernizing regulations and improving safety standards (D & C Rules 1945).

Recent Initiatives and Proposals

The draft OTC drug rules aim to regulate OTC medications, ensuring safety, efficacy, and quality while allowing their availability without a prescription. Key components include definition, classification, licensing, labeling, safety data, advertising, quality control, handling, storage, and distribution standards. The rules may increase costs for manufacturers, increase documentation requirements, improve safety information, and increase accessibility. Regulatory authorities may face increased responsibilities in licensing, inspections, and post-market surveillance. Healthcare professionals will receive better guidance and education on OTC products. The rules aim to balance accessibility with safety, efficacy, and quality, promoting safer, more effective OTC drug use.

Digital health uses technology to enhance healthcare services and outcomes, including telemedicine, health apps, EHRs, wearable devices, and AI. It aims to improve accessibility, efficiency, and quality while empowering patients to manage their health better. The rise of e-pharmacies is driven by internet penetration, smartphone use, and convenience. These services offer online prescriptions, home delivery, drug information, and consultations. However, regulatory challenges like drug safety compliance and counterfeit drugs remain. Future trends in digital health include technology integration, personalized medication plans, and expansion into new markets (Parker 2019, Nayyar *et al.*, 2018, Bhasker *et al.*, 2021, Verma *et al.*, 2017, and Aggarwal *et al.*, 2020).

Government policies and initiatives to enhance OTC drug regulation

The Indian government has a comprehensive regulatory framework for Over-the-Counter (OTC) drugs, including the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945. The CDSCO is responsible for approving and regulating OTC drugs, while state drug control authorities enforce regulations. Recent amendments have improved safety

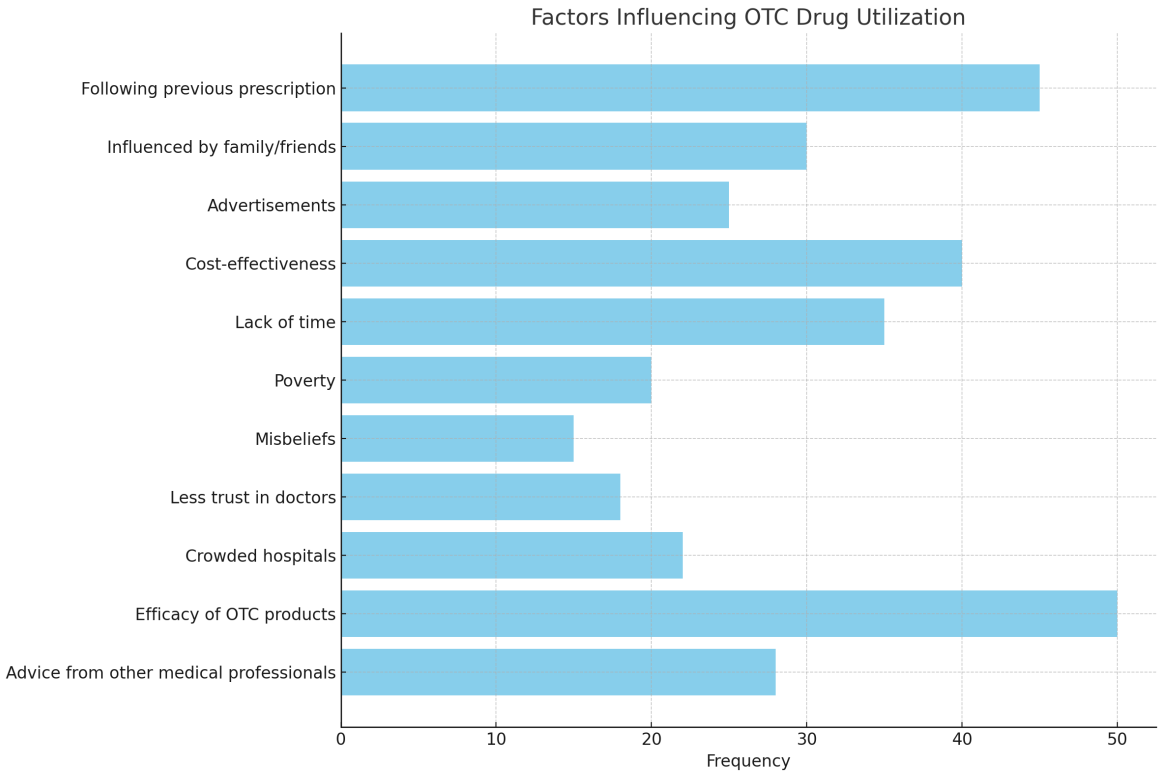

Figure 2: Factors influencing OTC drug utilization.

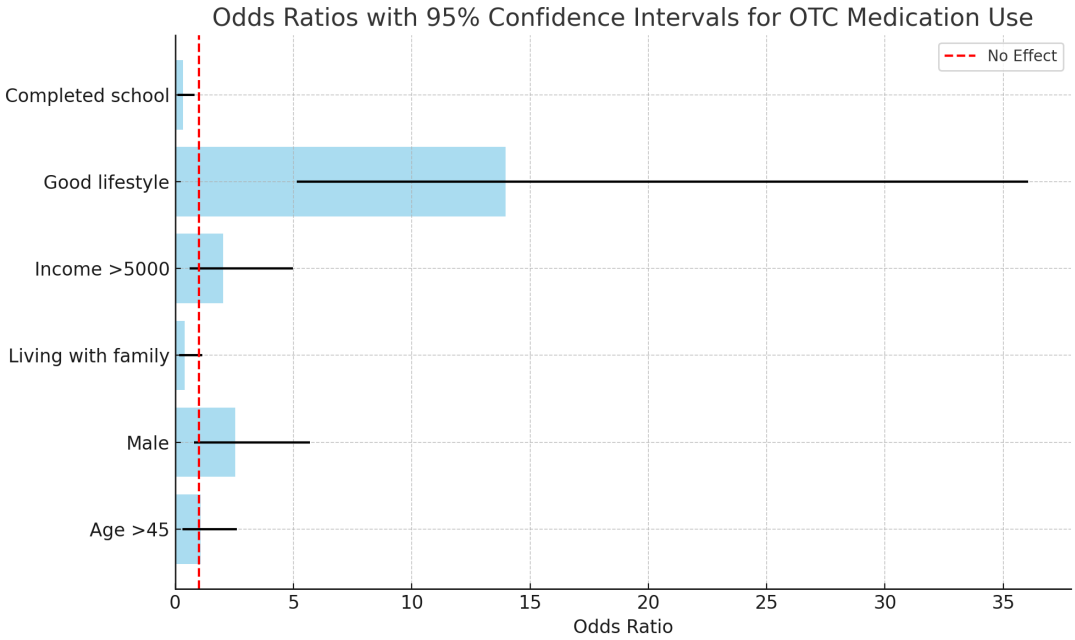

Figure 3: Demographic analysis of users.

standards, streamlined approval processes, and enhanced labeling requirements. Digital health initiatives, such as online drug licensing and registration, e-pharmacy regulations, and consumer protection campaigns, are also in place. Enforcement involves regular inspections, penalties, and corrective actions. Future initiatives will address emerging trends and technological advancements, ensuring public health and safety while facilitating access to OTC medications.

Challenges and Issues

OTC drug use can have negative consequences in several populations, including children, the elderly, pregnant and breastfeeding women, patients with other medical issues, and people on polypharmacy. According to a study (Martin BA, Breslow RM, Sims A, Harben AL), (Martin *et al.*, 2022). OTC drugs were the source of 6% of Adverse Drug Reactions (ADR) presentations to emergency rooms, and they were also responsible for one-third to half of ADRs that occurred because of self-administration. These findings raise concerns about the ADR rates connected to OTC drugs. For a variety of reasons, ADRs are more common in older persons. Medication use is more common among older persons than it is among younger adults. Polypharmacy rates have doubled during the last 20 years, and ADR rates have also increased at a similar rate.

The importance of regulating OTC drug intake is highlighted by case reports documenting Adverse Drug Reactions (ADRs) associated with these medications. For instance, a case study on ibuprofen, an anti-inflammatory drug available both over the counter and by prescription, reported that a patient experienced severe bronchospasm, throat, and laryngeal edema, leading to respiratory distress within 2 hr of ingestion. Despite being treated with salbutamol, hydrocortisone, Deriphylline, and supportive oxygen, the patient did not respond and eventually slipped into a coma. Unlike acetaminophen, ibuprofen lacks an antidote, making the management of its adverse drug reactions particularly challenging.

OTC drugs in elderly patients

An estimated 175,000 emergency department visits in the United States each year are related to pharmaceutical interactions between prescription and OTC drugs among adults 65 years of age and older. In India, a community-based cross-sectional survey on the use of Over-the-Counter (OTC) medications among senior individuals revealed that 51% of the elderly population used OTC drugs. Key factors contributing to this reliance included long hospital waiting times, travel distance to healthcare facilities, the perception of OTC medications as more effective treatment options, and financial constraints. Additionally, age-related physical impairments were commonly cited as a reason for OTC medication use. The healthcare system ought to prioritize serving the aged to make it more age-friendly and to provide geriatric patients with extra care. If not, this population, which is highly susceptible to ADRs or drug-related issues, will continue to depend more on OTC medications, a serious public health concern.

OTC drug in pregnancy

Pregnant women are another group at risk from the potentially negative effects of OTC medication. As this susceptible population is not included in clinical trials, the use of OTC medications during pregnancy creates public health concerns. Therefore, there is a lack of information regarding how these drugs affect such individuals. For instance, one study discovered

an association between an aspirin-using pregnant mother and cerebral haemorrhage in the foetus. Another study found a relationship between pregnant women who use valproic acid and their foetuses' higher risk of neural tube abnormalities (Aoyama *et al.*, 2020 and Davidson 2021).

OTC drugs in breastfeeding women

Drugs can have a significant impact on breastfeeding mothers and their infants, depending on factors such as drug transfer to breast milk, infant exposure, potential adverse reactions, and developmental impact. Most OTC drugs do not significantly alter the nutritional quality of breast milk, but it is essential to use medications that have been studied for safety during lactation. Pain relievers like acetaminophen and ibuprofen are generally safe, while cough and cold medications like pseudoephedrine should be used with caution.

OTC drug in polypharmacy

Polypharmacy, the use of multiple medications, can be challenging for various diseases due to potential drug interactions and side effects. Factors to consider include drug interactions, adverse reactions, lactation impact, and infant exposure. Safety measures when using Over-the-Counter (OTC) medications include avoiding high-risk drug combinations and monitoring for potential side effects. While pain relievers such as acetaminophen and ibuprofen are generally considered safe, caution should be exercised with decongestants, antihistamines, antacids, and laxatives due to their potential for adverse effects and interactions.

Regulatory enforcement, especially in rural and semi-urban areas

Regulatory enforcement in rural and semi-urban areas is challenging due to limited resources, infrastructure, and awareness. Factors include inadequate healthcare facilities, lack of consumer awareness about drug safety, and limited access to training programs. Geographic barriers and poor communication infrastructure also pose challenges. Counterfeit drugs increase the risk of entering the market. Strategies for effective enforcement include strengthening local infrastructure, enhancing awareness, improving access, collaborating with NGOs, and implementing authentication tools. Successful models include the National Health Mission, state-level programs, mobile health clinics, and community health workers, aiming to improve healthcare delivery in rural areas (Kotwani *et al.*, 2021).

Antibiotic resistance and other public health concerns

Antibiotic resistance is a growing concern, causing bacteria to develop mechanisms to withstand antibiotics, leading to treatment failures, prolonged illness, increased healthcare costs, and higher mortality rates. Causes include overuse, misuse, inadequate infection control, and lack of new antibiotics. Mitigation strategies include antibiotic stewardship programs, public education, regulation, infection control measures, and research. Challenges include vaccine hesitancy and inadequate vaccination coverage. Non-communicable diseases, such as heart disease, diabetes, and cancer, are also a concern. Mental health issues, such as depression, anxiety, and substance abuse, are also a concern. Environmental health impacts include air and water pollution, climate change, and exposure to hazardous substances.

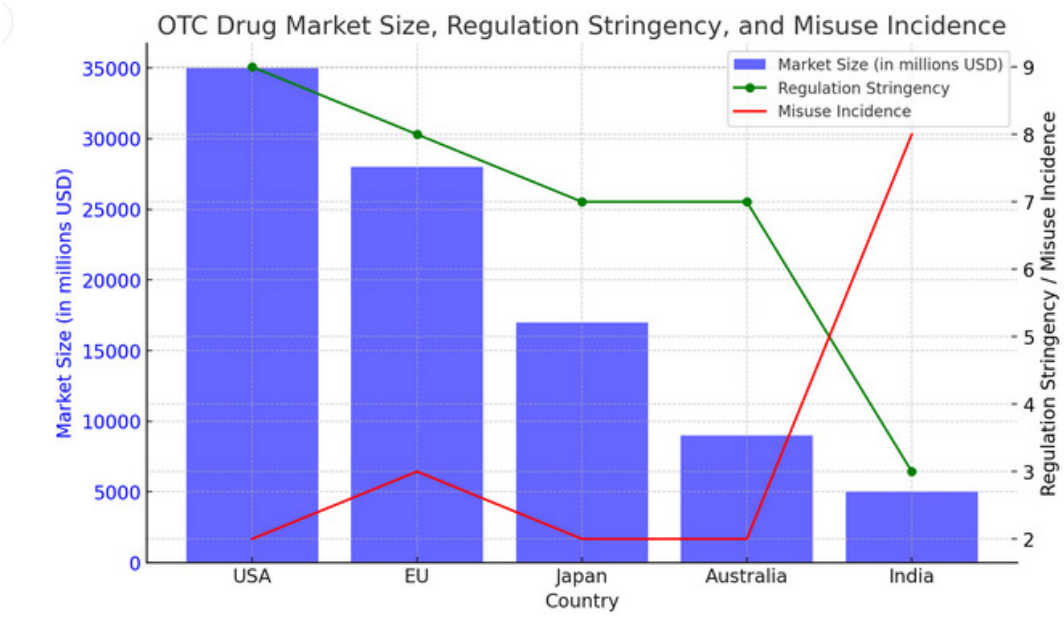

Figure 4: Comparative analysis with other countries' OTC drug regulations.

Global health security involves coordinated international responses, equitable access to vaccines and treatments, and strengthening health systems. Key initiatives include global collaborations, national and local efforts, research and innovation, and technology integration (Marathe *et al.*, 2020).

Comparative analysis with other countries' OTC drug regulations

Histo-diagram depicting the OTC drug market size, regulation stringency, and misuse incidence across different countries (Figure 4). The USA dominates the OTC drug market, followed by the EU, Japan, Australia, and India. The highest regulation stringency is in the USA, while the lowest misuse incidence is in the USA, Japan, and Australia. Countries with stricter regulations tend to have lower misuse incidence, emphasizing the need for robust OTC drug regulations. The OTC drugs market, valued at over USD 162 billion in 2022, is projected to grow at a CAGR of over 5% from 2023 to 2032, reaching USD 266 billion by 2032. The market is driven by the shift from prescription drugs to OTC drugs and increasing self-medication trends, particularly in developing economies. Key segments in the Over-the-Counter (OTC) product market include cold and cough remedies, gastrointestinal products, analgesics, as well as vitamins and dietary supplements. The Asia-Pacific region is emerging as the fastest-growing market, with its OTC segment projected to exceed USD 108 billion by 2032. Regulatory measures aim to promote rational drug use and public health, but misuse and abuse remain significant public health issues requiring public education and improved information infrastructure. OTC Sales in Different Countries: A Meta-Analysis (Narang *et al.*, 2023) (Table 1).

DISCUSSION

The Over-the-Counter (OTC) drug market in India is growing due to increased healthcare awareness, disposable incomes, and expanded access to healthcare services. Common OTC drugs include analgesics, antacids, cough and cold medications, vitamins, and dietary supplements. However, accessibility and availability are limited in rural and semi-urban areas due to fewer pharmacies and distribution challenges. The Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, are the primary legislation governing drug regulation in India. Recent developments include the growth of e-pharmacies, new regulations, policy updates, and participation in global health initiatives. Challenges include counterfeit drugs, regulatory gaps, and public health implications like self-medication risks and adverse reactions (Marathe *et al.*, 2020 and Aggarwal *et al.*, 2020).

India's recent regulations for OTC drugs are a shift towards a more consumer-oriented approach, aiming to improve consumer safety, expand access to medications, boost demand for the pharmaceutical industry, strengthen pharmacovigilance, and pose challenges for manufacturers and retailers. Stricter regulatory oversight will enhance safety, while clearer labeling and packaging will provide consumers with information about

Table 1: OTC Sales in Different Countries: A Meta-Analysis.

Country	Regulation	Sales and uses	Common OTC Drugs
United States	The FDA regulates OTC drugs, ensuring they meet safety, efficacy, and labeling standards. There are over 80 therapeutic classes of OTC drugs available.	The U.S. has a significant OTC market with widespread availability. OTC drugs are accessible in pharmacies, supermarkets, and online platforms.	Pain relievers (e.g., ibuprofen), antihistamines, cough and cold medications, and digestive aids.
European Union	The EU classifies OTC drugs into pharmacy and general sales medications. Regulations vary by member country but generally ensure strict safety and efficacy standards	High usage of OTC drugs across Europe, with an emphasis on self-care and minor ailment treatment.	Pain relievers, allergy medications, and gastrointestinal treatments.
Japan	Japan categorizes OTC drugs into three classes based on risk levels. The Ministry of Health, Labour, and Welfare oversees these regulations.	The OTC market in Japan is robust, with many products available through pharmacies and licensed retailers.	Cold and flu medications, digestive aids, and vitamins.
Australia	The Therapeutic Goods Administration (TGA) regulates OTC drugs, dividing them into pharmacy medications, pharmacist-only medications, and general sales medications.	High availability and usage of OTC drugs, with a strong emphasis on pharmacist guidance.	Pain relievers, allergy medications, and digestive aids.
India	India lacks specific guidelines for OTC drug categorization. Any drug not under prescription drug schedules (H, H1, X) is often sold OTC.	High incidence of self-medication due to easy availability and lower costs. This has led to significant misuse and safety concerns.	Painkillers, cough syrups, antacids, and antibiotics (often sold OTC despite regulations).

dosage, side effects, contraindications, and safe usage. Expanded access to medications could reduce the need for prescriptions for minor ailments, enhancing self-care and reducing healthcare burden. Market growth is expected as more drugs are approved for non-prescription sales, encouraging innovation and investment in pharmaceutical companies. Strengthened pharmacovigilance will be crucial for better tracking of drug safety post-marketing. Improved reporting systems will enable faster identification of issues and potential product recalls if safety concerns arise. Challenges for manufacturers and retailers include increased compliance costs related to new packaging, labelling, and monitoring requirements, limited retail sales, and reduced prescription drug dependence. Uniformity in drug enforcement will help avoid regional discrepancies in drug quality and availability, leading to more consistent access to safe OTC drugs. Important impacts on public health include better access to preventative care, reduced risks of self-medicine, stricter control over drug advertising, and increased consumer trust in OTC products. Modernising OTC drug regulations aligns India more closely with global standards, potentially increasing its competitiveness in the international pharmaceutical market (Verma *et al*., 2017, Sharma *et al*., 2018, Thorson *et al*., 2019, Nayyar *et al*., 2018, Dureja *et al*., 2021 and Ria *et al*., 2024).

The global Over-the-Counter (OTC) market is expanding due to health awareness, aging populations, and self-care practices. Countries with stricter regulations have better control over misuse and adverse effects. Misuse and abuse of OTC drugs are common, with higher incidences in regions with less stringent regulations. The U.S. and EU have comprehensive regulatory frameworks, but countries like India need more structured guidelines to prevent misuse. Public perception of OTC drugs as safer than prescription drugs leads to overuse. Effective public education campaigns and better labeling practices are essential to promote rational use. Pharmacists play a crucial role in guiding the safe use of OTC drugs, especially in well-regulated markets. Training and involving pharmacists in patient education can significantly reduce risks associated with OTC drug misuse (Rodrigues *et al*., 2021, Maugeri *et al*., 2023, and Basu *et al*., 2021).

Recommendations

The proposed legislation aims to create a separate legal category for Over-the-Counter (OTC) drugs within the Drugs and Cosmetics Act, separating them from prescription medications. This would provide clearer guidelines and tailored regulatory oversight. Strengthening pharmacovigilance and standardizing labelling and consumer information would improve self-medication safety. Enhancing regulations for online sales and implementing a tiered system of OTC drug approval based on risk profile would ensure safe and legal transactions. Increasing public awareness about the safe use of OTC drugs can empower individuals to use them responsibly. India needs to enhance regulations and consumer education to prevent misuse and abuse, improving public health outcomes. Implementing stricter regulations and promoting awareness can help mitigate issues related to high-risk OTC drug misuse. Fostering greater coordination between central and state regulators will ensure consistent enforcement of OTC regulations across the country. Stricter regulations on OTC drug advertising will prevent misleading or exaggerated claims, particularly for products targeting vulnerable populations. Regulating routine market surveillance and random inspections of OTC drug manufacturers, wholesalers, and retailers will help detect and eliminate unsafe or counterfeit OTC products from the market, improving overall drug quality and consumer safety. Facilitating accessibility to rural and underserved areas through mobile pharmacies, partnerships with local health workers, or incentivised retail outlets could also help reduce the burden on healthcare systems (Kumar *et al*., 2020, Verma *et al*., 2019, Patel *et al*., 2018, Singh *et al*., 2022, Kaur *et al*., 2017, and Vora *et al*., 2020).

CONCLUSION

India lacks a formal classification for OTC drugs, leading to confusion in regulation and enforcement. The CDSCO approves OTC drugs but lacks specific guidelines for online sales. The growing e-commerce sector increases access to OTC drugs, but a lack of clear regulations poses the risk of counterfeit products and unauthorized sales. Pharmacovigilance and safety concerns arise from the lack of knowledge about potential side effects and misuse risks. Labelling standards are inconsistent, leading to confusion and inappropriate self-medication. State drug control organisations play a crucial role in regulating OTC drugs across different states. Advertising and public awareness are also insufficiently regulated, leading to misleading claims and unapproved uses. India's future OTC drug regulation should balance accessibility, safety, innovation, and oversight. Collaboration between regulators, the pharmaceutical industry, and consumers is crucial for promoting safe self-medication practices, and meeting consumer needs while safeguarding public health.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

OTC: Over-the-Counter; **WHO:** World Health Organization; **FDA:** Food and Drug Administration; **NDA:** New Drug Application; **USFDA:** United States Food and Drug Administration; **D&C Act:** Drugs and Cosmetics Act (India); **CDSCO:** Central Drugs Standard Control Organization; **DCC:** Drug Consultative Committee; **EHRs:** Electronic Health Records; **AI:** Artificial Intelligence; **ADR:** Adverse Drug Reaction.

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