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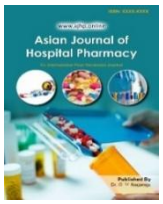

A REVIEW OF OVER THE COUNTER MEDICATION SAFETY, AFFORDABILITY, AND PREVALENCE

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Abstract

Over-the-counter (OTC) medications have become a cornerstone of modern self-care, allowing individuals to independently treat common ailments such as headaches, colds, and digestive discomfort without medical supervision. Their widespread availability offers substantial benefits-reducing unnecessary doctor visits, cutting healthcare costs, and empowering consumers to take control of their health. Globally, 60–80% of adults report using OTC products, with even higher rates in Europe and growing adoption across India and other low- and middle-income countries. Economic analyses show that every dollar spent on OTC drugs can save up to seven dollars in healthcare expenditure, highlighting their value to both individuals and health systems. However, the convenience of OTC access is coupled with significant risks. Misuse, accidental overdose, drug interactions, and inappropriate self-diagnosis contribute to adverse outcomes, particularly among vulnerable groups such as children, pregnant women, and the elderly. The misuse of antibiotics sold as OTC in some regions further fuels antimicrobial resistance-a major global health concern. Regulatory frameworks vary widely across countries, with strong safety controls in the US and Europe but substantial enforcement gaps in India and other developing markets. Education gaps also persist, as many users fail to read labels or underestimate potential side effects. This review evaluates the prevalence, benefits, risks, and regulatory challenges of OTC medication use. A balanced approach-strengthening regulation, enhancing pharmacist involvement, and improving public awareness-is essential to ensure that OTC drugs continue to support health without compromising safety.

Keywords: Over-the-counter medications, self-medication practices, Healthcare cost savings, Drug safety and misuse, Antimicrobial resistance, Regulatory challenges.

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Introduction

Over-the-counter (OTC) medications are drugs that can be purchased directly by consumers without a prescription. They play an increasingly central role in healthcare, enabling individuals to manage common ailments such as headaches, colds, gastrointestinal disturbances, and minor musculoskeletal pain. The World Health Organization (WHO) recognizes self-medication with OTCs as an important component of self-care, emphasizing its potential to empower patients, reduce the burden on healthcare systems, and promote more efficient use of medical resources. As populations worldwide move toward greater health autonomy, OTC medicines have emerged as both a symbol and a driver of this transition [1].

Historically, the development of OTC medications can be traced back to the era of "patent medicines" in the 19th century. These products, often marketed as universal cures, sometimes contained undisclosed-and harmful-ingredients. Public health crises resulting from their misuse led to regulatory interventions, beginning with early laws such as the U.S. Pure Food and Drugs Act of 1906 and evolving into

modern oversight systems like the FDA monograph process and equivalent regimes in Europe. In Europe, strict labelling and pharmacist-supervised dispensing have shaped safer use, while in India the absence of a formal OTC classification continues to allow prescription-only drugs to circulate more freely without medical oversight. This divergence in regulatory frameworks has contributed to regional differences in self-medication behaviour [2].

In the modern era, OTC medicines are deeply integrated into self-care practices. Factors such as rising healthcare costs, limited insurance coverage, long waiting times for consultations, and widespread availability through retail and online platforms have accelerated their use. The COVID-19 pandemic further reinforced this trend, with increased demand for vitamins, immune boosters, and symptom-relief products. Systematic reviews report a wide prevalence range of self-medication during COVID-19-from as low as ~7 % to over 80 %, depending on country and study setting. In lower- and middle-income countries, prevalence is often very high; for example, one study in Saudi Arabia reported 78.6 % prevalence of self-medication in its sample [3].

The economic impact of OTC medications is substantial. In the U.S., models estimate that OTC self-care yields savings of over USD 100 billion annually, accounting for both reduced physician visits and lower prescription expenditures. Review of Rx-to-OTC switches supports the idea that such switches often deliver cost savings to payers and patients in multiple settings. In Italy, a case study modelling prescription delisting projects savings via avoided GP visits and reduced drug spending under a societal perspective [4].

However, OTC medicines carry risks too. Inappropriate use, erroneous self-diagnosis, unrecognized drug interactions, and misuse can lead to serious harm. For instance, NSAIDs are linked with upper gastrointestinal injury and bleeding, and paracetamol (acetaminophen) overdose remains a leading cause of acute liver injury globally. In settings where antibiotics are available OTC, misuse exacerbates antimicrobial resistance (AMR). Vulnerable populations-including children, older adults, and pregnant women-are especially susceptible to dosing errors, polypharmacy risks, and potential developmental/teratogenic effects [5].

This dual nature of OTC drugs-as enablers of access yet potential sources of harm-underscores the need for strong regulatory frameworks, vigilant pharmacovigilance, and informed consumer behaviour. This review aims to examine the prevalence of OTC use, its economic implications, and associated safety challenges.

Importance of OTC Medications

Over-the-counter (OTC) medications are not merely convenient products; they form the cornerstone of self-care, serving as the initial frontline defense against common illnesses and minor health issues worldwide [6]. Their significance can be examined through three key perspectives:

1 Empowering the Consumer

OTC drugs have fundamentally shifted the power balance in healthcare, placing greater control directly into the hands of individuals. They enable people to actively manage their own health by treating minor, self-limiting conditions—such as headaches, colds, and seasonal allergies—immediately and effectively without requiring a doctor's appointment [7]. This accessibility is perceived by consumers as a vital part of autonomy and convenience, fostering greater health literacy and self-reliance [8].

2 Relieving the Healthcare Burden

One of the most profound benefits of OTC medicines is their massive contribution to the efficiency and cost-effectiveness of health systems globally. By allowing individuals to manage minor ailments themselves, OTCs prevent millions of unnecessary visits to primary care physicians and emergency rooms [9]. Economically, this translates into tangible savings. For instance, studies in the U.S. health system show that OTC medicines can generate huge cost savings when substituting prescription drugs or avoiding physician visits [10]. The steady process of Rx-to-OTC switches continues to expand this benefit by making proven, high-safety-margin medicines more accessible, further driving down societal costs [11].

3 Facilitating Immediate Care

In many parts of the world, especially in low- and middle-income countries (LMICs), OTC medications often represent the only readily available form of treatment [12]. They offer immediate time-to-treatment for acute symptoms, which can prevent minor issues from escalating into serious ones. Even in well-resourced environments, the presence of OTC products ensures continuous care, allowing people to manage common discomforts and chronic symptoms (like mild pain or heartburn) promptly and affordably, ensuring minimal disruption to their daily lives [13].

Prevalence of OTC Drug Use

The use of over-the-counter (OTC) medications is a widespread global health practice, with prevalence remaining high in many populations [14].

1 Global Prevalence

Recent studies show that roughly 40–60 % of adults globally report using OTC medicines for self-treatment of minor ailments. During the COVID-19 pandemic, prevalence increased further, especially for immunity-supporting OTCs and pain/fever relievers [15].

2 Regional Variations

- In India, a systematic review reported that about 64 % of the population practices self-medication, with even higher rates among university students. [16]
- In sub-Saharan Africa, antibiotic self-medication is common, in part due to regulatory gaps and easy pharmacy access. [17]

3 Population Subgroups

- Pregnant women: A meta-analysis found that approximately 36 % of pregnant women globally use

OTC medications, with analgesics and antacids being particularly common. [15]

- Children: A U.S. surveillance study showed that medication errors are a significant issue with OTC cough and cold medicines in children; about 10.8 % of adverse events involving these medications were due to dosing errors. [18]

4 Trends

The COVID-19 period amplified OTC usage in many regions, particularly for supplements and symptomatic relief. There's also increasing concern about antibiotic misuse and dependence associated with OTC medicines in some LMICs. [15][17]

Table 01: Prevalence of OTC Drug Use widespread global health practice.

SUBGROUP	Global/Regional Prevalence Estimate	Common Categories Used	Associated Risk
Global Adults	60% to 80%	Analgesics, Cough/Cold, GI	Misuse, delayed diagnosis
EU Nations	> 90%	Analgesics, Vitamins	Drug-Drug interactions
Older Adults	≈ 30% of total OTC use	Analgesics, GI, Supplements	Polypharmacy, ADRs, DDIs
LMICs/India	Highly variable (8% - 92%)	Analgesics, Antibiotics, Antimalarials	Antibiotic misuse, incorrect dosage

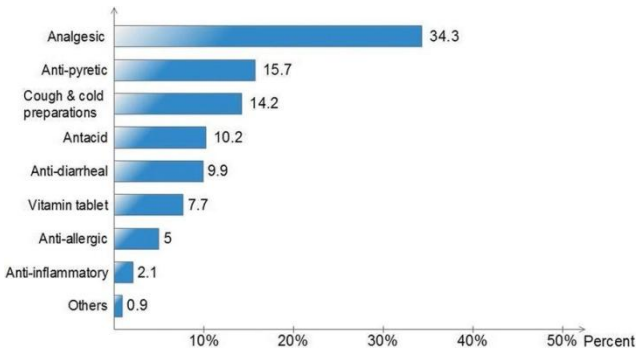

Fig 01: Most preferred drug classes by respondents for self-medication [47]

Patterns and Determinants of OTC Use

The practice of self-medication with OTC drugs is shaped by a confluence of product availability, economic factors, cultural beliefs, and health system characteristics [19].

1 Common Categories

- Analgesics and Antipyretics: Paracetamol and NSAIDs are among the most common OTC categories, particularly for headache, joint pain, fever, and musculoskeletal discomfort [20].
- Cough, Cold, and Flu Remedies: These see seasonal spikes in demand, with antihistamines, decongestants, and antitussives commonly purchased without prescription during cold/flu seasons.
- Gastrointestinal (GI) Medications: Antacids and other GI OTCs are widely used for heartburn, indigestion, and occasional constipation.
- Vitamins, Minerals, and Supplements: The market for preventive OTCs (vitamins, minerals) is rapidly expanding globally as consumers become more health-aware and invest in wellness [21].

2 Determinants

- Economic Drivers: Cost savings and avoiding physician visits lead many to choose OTC options when feasible [22].
- Cultural Attitudes and Convenience: Prior experience with OTC medicines, perceived mildness of ailments, and influence from family or media guide consumer behaviour [23].
- Health System Gaps: Poor access, long waiting times for doctors, and limited healthcare in rural areas increase reliance on self-treatment.
- Pandemic Effect: COVID-19 heightened awareness of minor symptom management and preventative health, increasing demand for OTCs and supplements for immune support [19-21].

Economic Impact of OTC Drugs

OTC drugs constitute a significant global market, delivering measurable economic benefits to consumers and health systems alike [25].

1 Market Growth

The global OTC drugs market continues to expand robustly. In 2024, the market was estimated at USD 180 billion, with projections indicating continued growth toward USD 302.3 billion by 2034. The compound annual growth rate (CAGR) was estimated at around 5–6% over this period [26]. Growth is especially strong in Asia-Pacific and in India, fuelled by rising disposable incomes, greater health awareness, and sheer population scale. The process of switching prescription drugs to OTC status (Rx-to-OTC) further fuels this expansion [27].

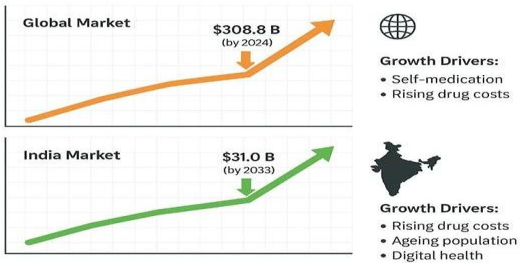

Fig 02: Global and India OTC Market Growth Projection

2 Cost Savings

One of the most compelling economic benefits of OTC medicines lies in cost avoidance. In the U.S. context, studies suggest that each dollar spent on OTCs may save the healthcare system $6 to $7 by reducing physician consultations and downstream interventions [28]. A major U.S. analysis estimated total annual savings of about USD 102 billion when OTC options were used instead of prescription alternatives [25]. These savings are especially impactful in publicly funded healthcare systems, such as those in Europe or India, where greater self-medication reduces system load.

3 Consumer Expenditure

While OTC products are broadly affordable, the burden may be meaningful for low-income populations, particularly in regions where insurance coverage is limited. Misuse or delayed diagnosis due to self-treatment may mask serious disease, resulting in higher long-term costs and complications.

4 Pharmacy & Industry Perspective

From an industry standpoint, the Rx-to-OTC switch strategy allows pharmaceutical companies to extend product life cycles and reach consumers directly. The rise of e-commerce and online pharmacies has accelerated OTC adoption by offering enhanced convenience and competitive pricing, though this trend raises concerns about counterfeit products and regulatory oversight [27][28].

Table 02: Economic Impact of OTC Drugs.

Region	Market Size (Approx. Annual value)	Estimated CAGR	Key Economic Impact
Global	> $180 Billion	≈ 5.7% (Forecast Period)	Reduces burden on primary care
U.S.	≈ $50 Billion (2024)	≈ 6.0%	$6 - $7 savings per $1 spent
Europe	≈ 53.5 Billion (2024)	Driven by aging population	Comprehen sive public healthcare savings
Asia-Pacific	High Growth Rate	Rapid	Driven by resign income and awareness

Safety Concerns and Adverse Effects

Although OTC medications generally have favourable safety profiles under recommended use, their widespread availability leads to nontrivial risk of harm when misused or used long term [29].

1 Adverse Drug Reactions (ADRs)

- NSAIDs (Ibuprofen, Naproxen): Chronic or high-dose use is linked to gastrointestinal bleeding, ulceration, renal impairment, and increased cardiovascular risk even at modest doses [30][31].
- Paracetamol (Acetaminophen): It remains a leading cause of acute liver failure in many high-income countries, often due to unintentional overdose from multiple products containing paracetamol [32].
- Antihistamines (First-generation): These agents carry anticholinergic side effects including sedation, dry mouth, and cognitive impairment, and are considered potentially inappropriate in older adults.
- Supplements: Quality and safety issues include contamination, variable potency, and risks of overdose of fat-soluble vitamins (e.g. vitamin A or D), especially when combined with other sources

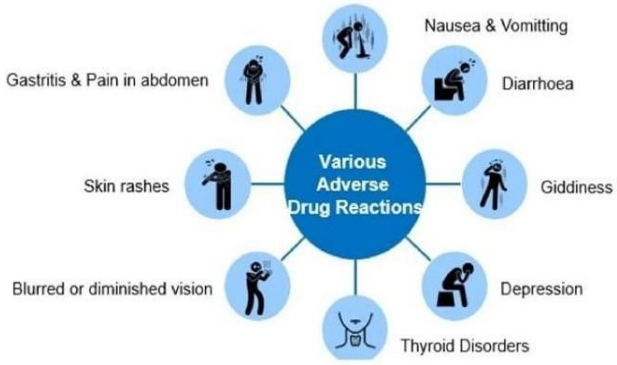

Fig 03: Common Adverse Drug Reaction Associated with OTC Medication Use.

2 Drug Interactions (DDIs)

- **Warfarin + NSAID:**
  Co-use increases bleeding risk through additive GI mucosal injury and interference with clotting mechanisms. Clinically relevant NSAID–warfarin interactions are well documented [30].
- **Antihistamines + Sedatives/Alcohol:**
  Co-administration potentiates central nervous system depression, increasing fall risk, confusion, and sedation.
- **Decongestants (e.g. pseudoephedrine):**
  In individuals with hypertension or cardiovascular disease, these OTC sympathomimetics can elevate blood pressure and heart rate dangerously.

3 Misuse & Abuse

- **Dextromethorphan (DXM):**
  At supra-therapeutic doses, DXM has dissociative and hallucinogenic properties ("robo-tripping"), leading to abuse in some populations.
- **Codeine or compound analgesics:**

These opioid-containing products risk dependence, overdose, and chronic organ damage from the non-opioid components (e.g. paracetamol, NSAIDs).

- **Antihistamines & Laxatives:**
  Misuse for sedation or weight control contributes to adverse effects including electrolyte disturbances, bowel injury, and toxicities.
- **OTC Antibiotics misuse:**
  Overuse of antibiotics without prescription is a key driver of antimicrobial resistance (AMR), especially in countries where OTC antibiotic sales persist [15].

4 Vulnerable Populations

- **Elderly:**
  Increased susceptibility to ADRs, polypharmacy interactions, and heightened sensitivity to anticholinergic/sedative effects.
- **Children:**
  Higher risk of dosing errors, accidental ingestion, and narrow therapeutic margins for agents like paracetamol.
- **Pregnancy/Lactation:**
  Limited safety data for many OTC medications necessitates medical supervision, as fatal exposure risks cannot always be excluded.

Table 03: Safety Concerns and Adverse Effects..

Major OTC Category	Primary Safety Risk	Example Misuse/Abuse	DDI/Contraindication Example
NSAIDs (Ibuprofen)	GI bleeding, Renal impairment	Chronic high-dose use for minor pain	Warfarin (Increased bleeding)
Paracetamol (Acetaminophen)	Acute Liver Failure (Overdose)	Combining multiple cold/pain products	Chronic Alcohol use (Increased liver toxicity)
Cough/Cold (DXM, Pseudoephedrine)	Psychoactive effects, Cardiovascular	High-dose "robotripping" for euphoria	Hypertension (Pseudoephedrine)
Sedative Antihistamines	Drowsiness, Cognitive impairment	International abuse for sedation	Alcohol/Sedatives (Enhanced CNS depression)

Regulation and Policy Frameworks

Effective OTC drug regulation is essential for balancing consumer access with public safety, though models vary significantly worldwide [33].

1. Global Models

- In the U.S., the OTC Monograph system defines classes of OTC drugs via conditions for ingredients, labelling, and dosing. The CARES Act (2020) added Section 505G, enabling FDA to issue administrative orders rather than relying solely on rulemaking for updating monographs, and established user-fee support ("OMUFA") to fund these operations [34][35].
- In the EU, Directive 2001/83/EC authorizes each Member State's competent authority to regulate the switch of medicines from prescription to non-prescription status, and to assign supply categories like "Pharmacy Only" vs "General Sales" [36].
- In India, though the CDSCO regulates drugs under the Drugs & Cosmetics Act, 1940, there is no legally codified national "OTC" definition—leading to ambiguous enforcement and the common but unauthorized dispensing of prescription medications without prescriptions.

Table 04: Regulation and Policy Frameworks.

USA	INDIA
• Structured OTC laws • FDA Monograph System • Clear Drug Classes (e.g. Pain Relief, Cough/Cold) • Labelling Requirements (Drug Facts Panel) • Pharmacist Discretion (Rx-to-OTC Switches)	• No formal OTC category • Drugs sold as "General Sales List" • Less Stringent Regulations • Blurred Lines: Rx & Non-Rx • Retailer Discretion in Sales

2 Labelling and Pharmacist Role

- EU Directive 2001/83/EC mandates that labels and leaflets be written "in such a way as to be clear and understandable" to users, which is central to enabling safe self-selection [36].
- Pharmacists play a critical gatekeeping role in many systems, especially where OTC status requires pharmacist consultation; they can help screen for drug-drug interactions, counsel consumers, and restrict inappropriate sales.

Fig 04: OTC Medication Safety Wheel-Key Steps for Responsible Self-Medication.

Online Pharmacies and Policy Responses

- The growth of online pharmacies has escalated the risk of counterfeit or poorly regulated OTC product sales across borders, bypassing traditional safeguards.
- Regulators are responding: the FDA's proposed "Additional Condition for Nonprescription Use" (ACNU) rule would allow certain OTC drugs to be sold only if additional conditions (e.g. a digital

questionnaire or kiosk screening) are met to ensure safe self-selection [34-37].

Public Knowledge, Attitudes and Practices (KAP)

Public knowledge, attitudes, and practices surrounding OTC use reveal significant gaps that undermine the safety and effectiveness of self-care.

1 Awareness Gaps, Low Label Reading

- Many consumers fail to read or fully comprehend OTC drug labelling; a Korean study found adults read only about 59% of label contents on average, with misunderstanding of ~20% of technical words—this gap was strongly associated with lower health literacy and education level. [38]
- In Saudi Arabia, while ~79.5% of surveyed individuals were aware of potential drug interactions, only ~29.5% believed OTC medications are safe without prescription; ~15.5% reported exceeding recommended dosages, and ~66% admitted sharing medications. [39]
- Among medical undergraduates in India, 62.5% indicated they know what to read on drug labels, yet many still use prescription-only medications as OTCs and have incomplete understanding of regulatory issues. [40]

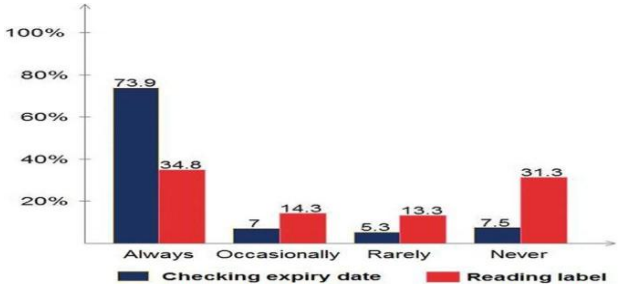

Fig 05: Habit of checking expiry date and reading labels of the respondents [47].

8.2 Need for Education Campaigns

There is strong support among public and professional groups for targeted education: improving awareness of active ingredients, interactions with other drugs or alcohol, and risks of long-term OTC use—especially for drugs like NSAIDs. [38][40]

8.3 Pharmacist-led Interventions

Studies show pharmacist-led educational or counselling interventions can significantly improve knowledge, attitudes, and practices: e.g., a pilot study found improved patient-pharmacist OTC encounters and safer OTC selection following redesign of pharmacy layouts or counselling interventions. [41]

Pharmacovigilance & Surveillance

The post-marketing surveillance of OTC drug safety is essential but is often compromised by significant underreporting of Adverse Drug Reactions (ADRs) [42].

1 Underreporting of OTC Adverse Events

- ADRs associated with OTC drugs are underreported more severely than those from prescription drugs, due in part to misattribution of symptoms or consumers believing OTCs are benign [43].
- Many consumers are unaware of how to report ADRs or that reporting even exists; healthcare professionals also face barriers like time constraints and uncertainty about what should be reported [44-45].

2 Strengthening Safety Reporting Systems

- Efforts to increase ADR reporting include promoting direct consumer reporting channels and simplifying reporting procedures [42].
- Pharmacists and point-of-sale staff have been identified in studies as key professionals who could be mandated or encouraged to report OTC drug-related ADRs, especially as they see many self-medicating consumers [43].

9.3 Digital / Pharmacy-based Monitoring

- Pharmacy networks and retail data systems represent underutilized sources for tracking OTC safety signals that don't reach central authorities [46].
- Surveys of pharmacists suggest that information on over-the-counter label content and critical safety warnings could be prioritized to reduce ADR risk among older adults [46].

Research Gaps and Future Directions

Despite the high usage rates and significant economic impact of the global self-care market, several critical research gaps remain that must guide future investigation and policy development:

Research Gaps

Lack of Long-term Safety & Economic Evaluations

There is a scarcity of long-term safety and cost-effectiveness evaluations of chronic OTC use, especially for conditions that should ideally be monitored by a physician. Most studies focus on short-term safety, neglecting the cumulative risk of long-term self-medication.

Scarce LMIC Data

Comprehensive, high-quality data on the prevalence, safety profile, and economic impact in Low- and Middle-Income Countries (LMICs) remains sparse and highly variable. This gap limits the ability of international organizations (like WHO) and local governments to formulate appropriate policies.

AMR Burden of OTC Misuse

Further research is urgently needed to quantify the burden of Antimicrobial Resistance (AMR) directly attributable to the misuse and non-prescription sale of antibiotics in LMICs.

Future Directions

Future research and policy efforts must focus on translating the potential of self-care into verifiable public health benefits through strategic investment:

Pharmacist-led Care Models

Evaluating the impact of mandatory pharmacist counselling and expanded prescribing rights for a wider range of minor ailments. Future models should centre on the pharmacist evolving from a dispenser to a clinically sharp, tech-ready advisor, maximizing their accessibility to improve treatment adherence and patient outcomes [17, 44].

- **Digital Tracking**
  Developing and standardizing digital tools and mobile applications to facilitate safe self-selection, track chronic consumption, and directly integrate with pharmacovigilance systems. This technological adoption is essential to bridge data gaps, streamline patient-pharmacist interaction, and enhance real-time safety signal detection [40, 47].

Conclusion and Future Directions

The self-care revolution, underpinned by the widespread availability and use of over-the Counter (OTC) medications, defines a major component of modern healthcare. The review has highlighted the extraordinary prevalence of OTC use globally, confirming its entrenched role in daily life and its significant, quantifiable economic impact through healthcare cost savings. This accessibility, however, presents a critical safety paradox. The benefits of convenience and cost are shadowed by risks stemming from user-based factors like low health literacy, incorrect self- diagnosis, and the misuse of potent ingredients, contributing to adverse drug reactions and the alarming rise of antibiotic resistance. Moving forward, the imperative is to strike a precise balance between access and public safety. This necessitates a coordinated global effort:

- A call for harmonized regulation-learning from robust systems like the US Monograph and the rigor of the EU switch process, while specifically addressing the unregulated environment of LMICs.
- Prioritizing education and awareness campaigns to empower consumers with the knowledge to read labels and understand risk.
- Strengthening pharmacovigilance and surveillance by leveraging digital tools and empowering the pharmacist as the primary gatekeeper to ensure safe, responsible self- care.

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No Conflict of Interest

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Author Contribution

All authors are contributed equally.

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