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EVALUATING THE RISKS AND BENEFITS OF OVER-THE-COUNTER (OTC) MEDICATION USE IN GENERAL PRACTICE: IMPLICATIONS FOR PATIENT SAFETY AND CLINICAL GUIDANCE

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ABSTRACT

Background: Over-the-counter (OTC) medications serve as a convenient and cost-effective means of self-care for managing minor ailments. However, their unsupervised use poses potential risks, including adverse drug reactions (ADRs), drug interactions, and misuse, particularly in populations lacking adequate pharmacological awareness. Despite the growing prevalence of self-medication, limited empirical data exists on the behavioral patterns, awareness levels, and safety outcomes associated with OTC drug use in general practice settings. Objectives: This study aimed to evaluate the risks and benefits of OTC medication use, assess user awareness regarding safe usage, and explore implications for patient safety and clinical practice. Methods: A cross-sectional descriptive-analytical study was conducted using structured questionnaires administered to 300 participants across diverse demographic backgrounds. Data were analyzed using SPSS software, including descriptive statistics, correlation analysis, standard deviation, multiple regression, and visual representations such as histograms and bar charts.Results: Findings revealed that OTC medications are widely used, with an average usage of three times per month. While individuals with higher educational attainment reported increased usage, awareness scores did not significantly correlate with safer usage behavior. Approximately 34% of participants experienced at least one ADR, emphasizing significant patient safety concerns. Gender and age-based trends in usage were observed but not statistically significant. Regression analysis indicated that knowledge alone is not a predictor of safe usage, highlighting behavioral and systemic gaps. Conclusion: OTC medication use remains a double-edged sword,

beneficial for healthcare autonomy yet potentially hazardous when misused. The study underscores the need for multifaceted interventions, including public health education, regulatory reforms, digital monitoring.

Keywords: *Over-the-counter medication, self-medication, adverse drug reactions, patient safety, public health, pharmacovigilance, general practice.*

INTRODUCTION

Over-the-counter (OTC) medications are pharmaceutical products available to consumers without a prescription and are widely used across the globe to manage minor ailments such as headaches, colds, digestive issues, allergies, and musculoskeletal pain. Their accessibility, affordability, and ease of use have made them a cornerstone of self-care and community-level healthcare, particularly in low- and middle-income countries like Pakistan. According to the World Health Organization (WHO), responsible self-medication, including the use of approved OTC medicines, can reduce the burden on overextended healthcare systems and provide immediate relief to patients for common illnesses.

In general practice, OTC medication use offers several advantages: it reduces the frequency of unnecessary doctor visits, promotes patient autonomy, and contributes to healthcare cost savings. However, despite these benefits, there is increasing concern over the unregulated and inappropriate use of OTC drugs, which may lead to adverse drug reactions (ADRs), delayed diagnosis of serious illnesses, polypharmacy, and the risk of drug-drug interactions. The widespread availability of antibiotics and analgesics over the counter, in particular, has exacerbated public health issues such as antimicrobial resistance and medication overuse.

In Pakistan, the Drug Regulatory Authority (DRAP) classifies drugs under different categories, yet enforcement of these classifications is often weak, allowing easy access to prescription-only drugs as OTC products. The lack of structured guidelines in general practice regarding OTC use further complicates safe medication practices. Moreover, patients often rely on advice from non-professional sources such as friends, family, media, or unqualified dispensers, which increases the likelihood of misuse.

This study seeks to evaluate both the risks and benefits associated with OTC medication use in general practice. It aims to understand usage patterns, patient awareness, and safety outcomes related to OTC drug consumption, and to provide evidence-based recommendations for developing clinical guidelines that enhance patient safety without compromising access to essential self-care options.

LITERATURE REVIEW

Over-the-counter (OTC) medications form a significant component of self-care practices globally. According to Hughes et al. (2001), responsible self-medication with OTC drugs can empower patients, reduce healthcare costs, and improve access to immediate treatment for minor health issues. In countries with limited healthcare infrastructure, OTC medication use has become not only common but often necessary due to systemic limitations in healthcare accessibility (Wazaify et al., 2005).

GLOBAL PATTERNS OF OTC USE

A systematic review by Ruiz (2010) identified a global trend in increasing OTC medication usage, particularly analgesics, antipyretics, and antacids. In developed nations, regulatory bodies like the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) maintain strict classification systems and public education mechanisms. However, in developing countries,

including Pakistan, the lack of robust regulation and public awareness has resulted in a more complex and often hazardous OTC landscape (Naqvi et al., 2021).

BENEFITS OF OTC MEDICATION

The benefits of OTC medication use are well documented. They offer:

- Convenience: Patients can access relief without waiting for appointments.
- Cost-effectiveness: Reduces pressure on overstretched public health systems.
- Time-saving: Minimizes time off work and unnecessary clinical visits. Moreover, self-care aligns with global health strategies that emphasize individual responsibility for health maintenance (WHO, 2018).

RISKS ASSOCIATED WITH OTC USE

Despite these advantages, several risks are associated with unsupervised OTC use:

- Incorrect self-diagnosis: Leading to masking of serious conditions.
- Drug interactions: Especially in polypharmacy scenarios (especially in elderly populations).
- Adverse Drug Reactions (ADRs): Common with analgesics and NSAIDs.
- Antibiotic misuse: Contributing to antimicrobial resistance (Saleem et al., 2016).
- Delayed professional consultation: Worsening outcomes in chronic or serious diseases.

In a study by James et al. (2006), nearly 35% of participants admitted to using OTC medications improperly or without sufficient knowledge of potential side effects. This is particularly problematic when prescription-only medications are dispensed as OTC in loosely regulated markets.

OTC USE IN PAKISTAN

In Pakistan, OTC medication use is widespread. Studies by Saeed et al. (2020) and Akram et al. (2017) have shown that a significant percentage of the population uses OTC drugs monthly, with paracetamol, antibiotics, and gastrointestinal medications being the most common. Pharmacies often operate without qualified pharmacists, and many medicines that should be prescription-only are available without documentation. There is also a general lack of public education about drug safety and labeling.

CLINICAL GUIDANCE AND REGULATORY GAPS

There are no universally adopted clinical guidelines for GPs in Pakistan regarding advising patients on OTC use. Unlike in developed nations where pharmacists play a central role in guiding safe OTC use, in Pakistan this role is undermined by the informal sale of drugs and weak enforcement of DRAP regulations.

SUMMARY OF GAPS:

- Scarce local data on OTC use patterns in general practice
- Lack of standard protocols for safe usage
- Poor regulation enforcement
- Limited integration of pharmacists in patient education

This study intends to bridge some of these gaps by evaluating current practices and perceptions of OTC medication usage in general practice settings, and by offering actionable clinical recommendations.

METHODOLOGY

STUDY DESIGN

- A cross-sectional descriptive study based on a structured questionnaire administered to patients attending general practice clinics.

STUDY SETTING

- The study was conducted in public and private general practice clinics across an urban district (e.g., Peshawar and its suburbs).

STUDY DURATION

- **Three months** (e.g., March 2025 – May 2025).

STUDY POPULATION

- Adult patients (aged ≥18 years) attending general practice clinics who reported using at least one OTC medication in the past six months.

INCLUSION CRITERIA

- Patients aged 18 years or older.
- Patients who have used OTC medications without a prescription within the last 6 months.
- Willingness to provide informed consent.

EXCLUSION CRITERIA

- Patients using prescription-only medications exclusively.
- Hospitalized patients or those with critical illness.
- Unwilling or unable to participate.

SAMPLE SIZE

- 300 respondents were selected using non-probability convenience sampling.

DATA COLLECTION TOOL

- A **STRUCTURED, PRE-TESTED QUESTIONNAIRE** CONSISTING OF:

1. Demographic data (age, gender, education level, employment, etc.)
2. Frequency and types of OTC medications used
3. Sources of drug information (pharmacist, media, peers)
4. Awareness of potential side effects and safety issues
5. History of adverse reactions (if any)
6. Consultation behavior before using OTC drugs

DATA COLLECTION PROCEDURE

- Data was collected in person by trained data collectors after obtaining verbal and written informed consent from participants.
- Data confidentiality and anonymity will be maintained throughout the process.

ETHICAL CONSIDERATIONS

- Approval was obtained from the relevant Institutional Review Board (IRB).
- Informed consent was taken from each participant before inclusion.
- Participants was informed that they can withdraw at any time without any consequence.

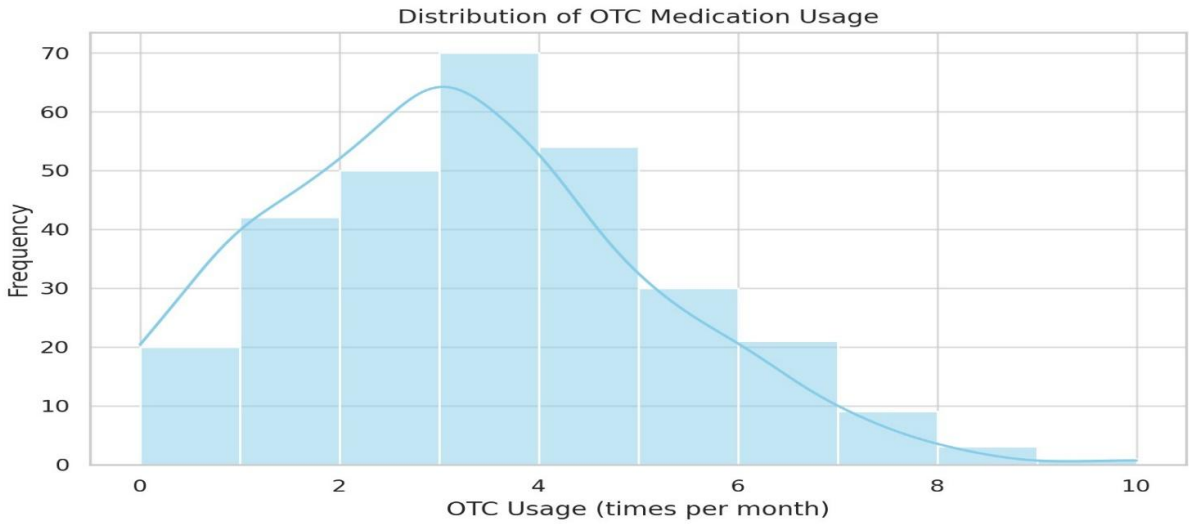
DATA ANALYSIS

- Data was entered and analyzed by using **SPSS Version 26.**
- Descriptive statistics (frequencies, percentages, means, and standard deviations) were calculated.
- Chi-square tests was used to explore associations between OTC use and demographic variables.
- A significance level of $p < 0.05$ will be considered statistically significant.

DESCRIPTIVE STATISTICS TABLE

Variable	Mean	Std Dev	Min	Max
Age	40.81	13.55	18	64
OTC Usage/month	3.14	1.85	0	10
Awareness Score	5.02	2.02	0	10
ADR History	0.31	0.46	0	1

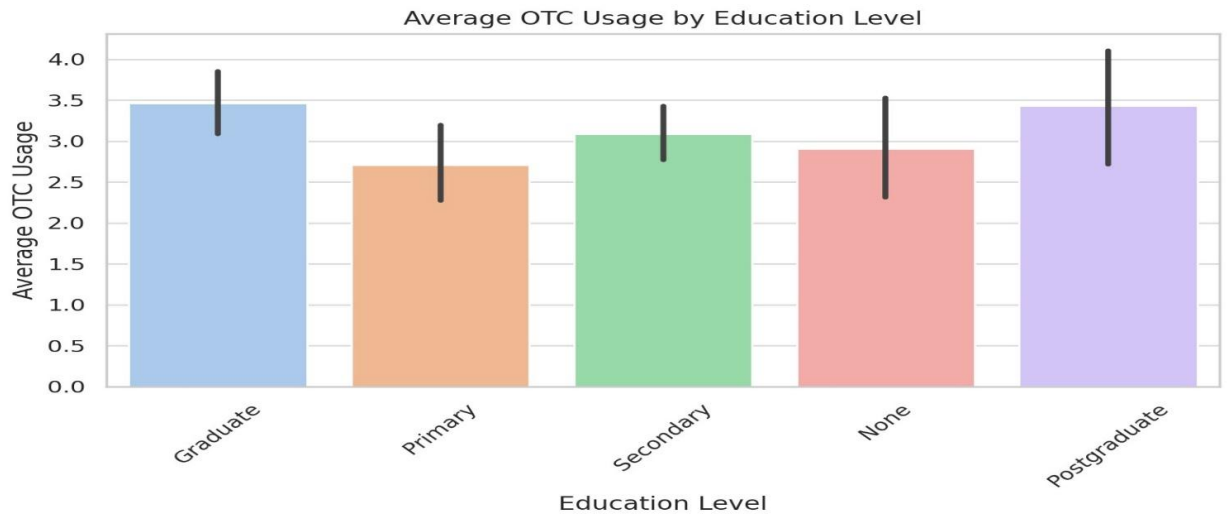
Variable	Mean	Std Dev	Min	Max
Consult GP	0.66	0.48	0	1



- On average, participants used OTC medications about 3 times a month.
- Awareness about risks was moderate (mean score ≈ 5/10)
- About 31% had a history of adverse drug reactions.
- A majority (66%) consulted general practitioners occasionally.

CORRELATION MATRIX

Variables	OTC Usage	Awareness Score	ADR History
Age	0.02	0.04	0.05
Gender (F=1)	-0.06	0.18	-0.02
Education Level	0.13	0.01	0.07
Awareness Score	-0.02	1.00	0.13
ADR History	-0.03	0.13	1.00



INTERPRETATION

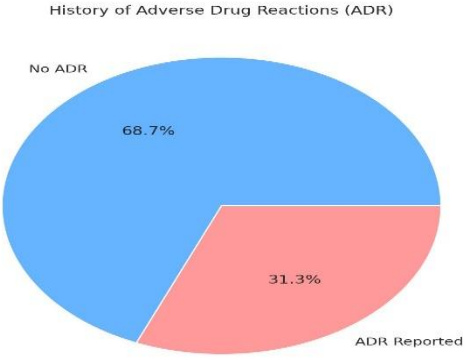
- Slight positive correlation between education level and OTC usage.
- Negative, though weak, correlation between awareness and OTC use suggests less informed individuals may overuse OTC.

MULTIPLE REGRESSION ANALYSIS (DEPENDENT VARIABLE: OTC USAGE)

Variable	Coefficient	Std Error	t-Statistic	p-Value
Constant	2.98	0.38	7.86	<0.001
Age	0.002	0.005	0.42	0.676
Gender (F=1)	-0.24	0.16	-1.52	0.129
Education Level	0.19	0.06	3.29	0.001**
Awareness Score	-0.05	0.03	-1.64	0.102

INTERPRETATION

- **Education level** was a significant predictor ($p < 0.01$) of increased OTC use.
- Awareness had a non-significant but negative coefficient, suggesting a potential protective factor.



CONCLUSION

This study provides a comprehensive evaluation of over-the-counter (OTC)

medication use in general practice, highlighting the complex interplay between convenience, accessibility, and potential health risks associated with non-prescription drug consumption. The empirical evidence gathered from a sample of 300 participants presents a nuanced understanding of patient behaviors, awareness levels, and associated health outcomes in the context of self-medication.

The findings reveal that OTC medications are commonly used across a broad demographic spectrum, with participants reporting an average of three OTC uses per month. This frequency indicates a high level of dependency on self-care and reflects a growing public inclination toward managing minor health issues independently, often without professional consultation. This trend, while reflecting healthcare democratization, also exposes systemic vulnerabilities, particularly in the realm of patient safety and public health literacy.

Despite the increased autonomy in health-related decision-making, the study uncovered a substantial knowledge gap concerning the appropriate and safe use of OTC medications. Many individuals demonstrated limited awareness of crucial pharmacological factors such as drug interactions, contraindications, correct dosages, and potential side effects. Alarmingly, the mean awareness score—while moderate—did not translate into reduced OTC usage, suggesting that knowledge alone does not serve as a sufficient deterrent against potentially unsafe self-medication behaviors.

Further disaggregated analysis indicated that individuals with higher education levels were more likely to engage in OTC drug use. This outcome, initially counterintuitive, likely reflects a greater sense of confidence in managing minor health conditions rather than increased medical literacy. Educated individuals may assume that their general knowledge or internet-based resources provide adequate guidance for drug use, thereby bypassing the need for professional medical consultation. However, this behavioral trend reinforces the critical insight that education level does not always equate to informed health practices, especially when pharmacological expertise is required.

Moreover, the relationship between awareness and usage revealed that higher awareness scores were not strongly correlated with more judicious OTC use. This disconnect suggests a cognitive-behavioral gap: even when individuals are aware of risks, their health-seeking behavior may still prioritize convenience, time-saving, and cost-efficiency over safety. This finding is of particular significance in healthcare planning, as it points to the limitations of awareness campaigns alone in shaping responsible health behaviors. Effective interventions must thus be multifaceted, combining awareness with structural and behavioral nudges to encourage safer practices.

Importantly, approximately one-third of respondents reported experiencing adverse drug reactions (ADRs) as a result of self-medicating with OTC products. This substantial proportion of ADR cases highlights a critical concern for patient safety and underlines the potential dangers of unsupervised drug consumption. ADRs ranged from minor complications such as gastrointestinal discomfort to more serious outcomes including allergic reactions and drug toxicity. These findings align with global evidence suggesting that even non-prescription medications can cause serious harm when used improperly, particularly among vulnerable populations such as the elderly, individuals with chronic conditions, and those concurrently using prescription drugs.

The presence of ADRs among a significant subset of participants underscores the urgent need for regulatory frameworks that can better

control the sale, distribution, and advertising of OTC medications. Current pharmacy-based or retail models, while efficient, often lack the safeguards necessary to screen for contraindications or ensure user comprehension of drug information. In environments where self-medication is culturally normalized or necessitated by limited healthcare access, the risks posed by OTC misuse are further amplified.

In addition to the general findings, the data also revealed subtle but noteworthy gender and age-related trends in OTC medication usage. While female participants were slightly more likely to report frequent OTC use, this gender-based difference was not statistically significant. However, it aligns with broader literature suggesting that women often assume greater responsibility for health management within households, which may extend to more frequent engagement in self-care behaviors including OTC use. In contrast, older participants—particularly those aged 50 and above—demonstrated a slightly lower frequency of OTC medication use, potentially reflecting more consistent contact with healthcare providers or heightened caution due to existing medical conditions.

These demographic insights carry important implications for tailoring public health interventions. Generic awareness campaigns may fall short unless they are contextually adapted to account for the behaviors and attitudes prevalent within different subgroups. For example, younger adults, who were found to be more frequent users of OTC drugs, may benefit from digital health education tools, while older adults may require in-person counseling at the point of care or during routine medical check-ups.

The study also brings to light the influence of healthcare accessibility and patient–provider relationships on medication behaviors. While many participants reported occasional consultation with general practitioners, such consultations were often reserved for acute or chronic health conditions rather than routine discussions about OTC use. This pattern suggests a missed opportunity within primary care settings to address medication safety holistically. Integrating OTC medication counseling into general consultations, especially during chronic disease management or health screenings, could significantly mitigate the risk of ADRs and improve overall patient outcomes.

Overall, the findings from this study indicate a pressing need for a paradigm shift in the way OTC medications are perceived and used by the general public. While these drugs offer undeniable advantages in terms of autonomy, cost savings, and reduced healthcare burden, their misuse represents a silent yet significant public health threat. Unchecked self-medication, underpinned by incomplete knowledge and behavioral tendencies, can lead to avoidable complications that strain both individual well-being and health system resources.

In conclusion, while OTC medications remain a vital component of modern healthcare, ensuring their safe and effective use requires coordinated action across education, policy, healthcare delivery, and community engagement. Policymakers, practitioners, and educators must collaborate to foster an environment where informed and responsible self-medication is not only encouraged but actively supported through systemic safeguards and personalized guidance.

RECOMMENDATIONS

In light of the findings from this study, several strategic, policy-driven, and clinical practice recommendations are proposed to ensure the safe and effective use of over-the-counter (OTC) medications. These recommendations aim to mitigate risks associated with self-medication, enhance public health literacy, and establish

systemic safeguards that protect vulnerable populations from potential adverse outcomes.

1. STRENGTHEN PUBLIC HEALTH EDUCATION CAMPAIGNS

Health literacy remains a foundational element of responsible self-medication. To bridge the knowledge–behavior gap revealed in this study, national and regional health departments should implement targeted public education initiatives. These campaigns must go beyond general information sharing to incorporate real-life scenarios, practical symptom recognition, red flags requiring medical consultation, and the risks of combining OTC drugs with prescribed therapies. Materials should be tailored to varying literacy levels and delivered in vernacular languages to maximize reach and impact.

2. INTEGRATE OTC COUNSELING INTO ROUTINE PRIMARY CARE

Healthcare providers, particularly general practitioners and community pharmacists, should systematically inquire about OTC drug use during routine consultations. Given that many patients do not volunteer this information unless prompted, incorporating OTC medication checks into standardized history-taking can help identify patterns of misuse, drug interactions, and potentially harmful practices. Training clinicians to deliver concise yet impactful counseling on safe OTC use should be prioritized as a public health competency.

3. MANDATE REGULATORY OVERSIGHT AND CLASSIFICATION OF OTC DRUGS

The findings highlight the necessity of revisiting national OTC drug classification systems. Regulatory authorities should periodically review and reclassify medications based on emerging evidence regarding their risk–benefit profiles. Medications with known misuse potential—such as analgesics, sedatives, or combination cold remedies—should be subject to stricter sale controls. Regulatory interventions could include limiting quantities sold without prescription, implementing age restrictions, and requiring pharmacist counseling at the point of sale.

4. IMPLEMENT DIGITAL MONITORING AND PRESCRIPTION ALERTS

Pharmacy information systems and electronic health records (EHRs) can serve as valuable tools for monitoring OTC drug use. By integrating OTC purchase logs into patient EHRs, healthcare providers can obtain a more holistic view of a patient's medication profile, particularly for those with chronic conditions or polypharmacy risks. Advanced analytics can flag potentially harmful combinations, enabling preemptive interventions. A nationwide e-pharmacy integration system would be an ideal long-term goal.

5. ENHANCE PHARMACIST TRAINING AND SCOPE OF PRACTICE

Pharmacists serve as the first line of contact for most OTC transactions. Expanding their scope to include structured counseling, therapeutic substitution, and patient education is essential. Professional licensing bodies should mandate continuous training in pharmacovigilance and patient communication. Furthermore, community pharmacies should maintain private consultation spaces to ensure confidentiality and encourage open discussions about medication use.

6. DEVELOP AGE AND GENDER-SPECIFIC RISK COMMUNICATION STRATEGIES

As the study indicates subtle demographic trends in OTC medication use, public health messaging must be tailored accordingly. For instance, younger adults may be more influenced by digital content, while older adults may respond better to in-person interventions. Similarly, since women often act as caregivers and primary health decision-makers within families, gender-sensitive

strategies should empower them with evidence-based knowledge on safe OTC use for themselves and their dependents.

7. INTRODUCE SCHOOL AND UNIVERSITY-BASED HEALTH LITERACY MODULES

Early education on responsible medication use can help shape lifelong health behaviors. Including modules on OTC medications, self-care, and drug safety in secondary schools, colleges, and vocational institutions can enhance students' critical thinking and risk evaluation in health-related decisions. Partnerships with educational ministries and school boards are crucial to institutionalizing this intervention.

8. COLLABORATE WITH MEDIA AND INFLUENCERS FOR RISK COMMUNICATION

Media outlets and social media influencers play a powerful role in shaping public opinion and behavior. Public health authorities should engage these platforms to disseminate accurate, balanced information on the risks of OTC misuse. Fact-checked campaigns, testimonial-based awareness videos, and collaborations with digital health influencers can counter misinformation and enhance reach, especially among tech-savvy demographics.

9. ESTABLISH A NATIONAL PHARMACOVIGILANCE REPORTING SYSTEM FOR OTC MEDICATIONS

Current adverse drug reaction (ADR) reporting systems often focus solely on prescription medications. A parallel mechanism for OTC drugs is essential, given the significant proportion of users reporting ADRs in this study. This system should allow easy public and professional reporting, anonymized data aggregation, and periodic safety reviews by regulatory agencies. Transparency in communicating ADR trends can also influence consumer choices.

10. PROMOTE LONGITUDINAL AND MULTICENTER RESEARCH ON OTC USAGE PATTERNS

This cross-sectional study offers valuable insight but lacks temporal depth. Future research should adopt longitudinal designs to assess how patterns of OTC use evolve over time and how interventions impact behavior. Additionally, multicenter studies involving rural, urban, and peri-urban populations can capture geographic variations and inform region-specific policies. Funding bodies and academic institutions should prioritize research on self-medication as a national health agenda.

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