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Complications Over OTC: A Comprehensive Analysis of Risks, Misuse, and Regulatory Challenges in Over the Counter Medications

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Abstract: ***Over-the-counter (OTC) medications are widely used for the management of minor and self-limiting health conditions due to their accessibility and convenience. However, inappropriate use in the absence of professional supervision has emerged as a significant contributor to preventable adverse health outcomes, particularly in low- and middle-income settings such as India. Misuse of OTC drugs commonly involves excessive dosing, prolonged consumption, polypharmacy, and failure to recognize contraindications or clinically relevant drug interactions. This review examines complications associated with the unsupervised use of commonly available OTC medications, including nonsteroidal anti-inflammatory drugs, antihistamines, antacids and acid-suppressing agents, cough suppressants, laxatives, and topical corticosteroids. The discussion integrates pharmacological mechanisms of toxicity with clinical evidence describing organ-specific adverse effects involving the gastrointestinal, renal, hepatic, cardiovascular, and neurological systems. Increased vulnerability among elderly individuals, pregnant women, children, and patients with chronic illnesses is highlighted. Regulatory challenges governing OTC medicines in India are critically evaluated in comparison with international practices, with emphasis on gaps in pharmacovigilance, labeling, and post- marketing surveillance. The role of community pharmacists in promoting rational OTC use through patient counseling and early risk identification is also discussed. Strengthening regulatory oversight and public health education is essential to reduce avoidable harm while maintaining therapeutic accessibility.***

Index Terms: ***Over-The-Counter Medications, Self-Medication, Adverse Drug Reactions, Pharmacovigilance, Public Health; Pharmaceutical Regulation***

I. INTRODUCTION

Over-the-counter medications occupy a distinctive position within global pharmaceutical systems, balancing consumer autonomy and therapeutic accessibility against medical safety considerations. The World Health Organization estimates that OTC medications account for 40–45% of total pharmaceutical consumption in developed nations and 25–35% in developing nations, with substantial heterogeneity based on healthcare system structure, regulatory sophistication, and economic factors [1]. In India, OTC drugs constitute approximately 32% of retail pharmaceutical sales by volume, yet pharmacovigilance systems capture only 3–5% of actual adverse drug reactions (ADRs) occurring in community settings [2].

The rationale for OTC availability includes reduction of healthcare system burden, cost containment, and consumer convenience for management of self-limited conditions. However, the absence of prescriber-mediated clinical assessment eliminates critical control points for identifying contraindications, drug interactions, and dosage modifications required in vulnerable populations. Contemporary epidemiological evidence demonstrates that OTC medications generate substantial morbidity and mortality: approximately 12,000 annual deaths attributable to OTC drug-related complications occur in the United States [4], with proportionally greater burdens in healthcare resource-limited settings where pharmacist oversight is minimal [3].

The Indian pharmaceutical regulatory environment presents particular challenges. The Drugs and Cosmetics Act (1940) and Drugs and Cosmetics Rules (1945), while foundational, were formulated preceding contemporary understanding of pharmacokinetics, pharmacodynamics, and drug interactions. The schedule classification system dividing drugs into categories from OTC to prescription-only provides insufficient granularity for managing evolving safety evidence [5]. Furthermore, approximately 35–40% of OTC

products sold in Indian pharmacies operate outside formal regulatory purview, with substandard formulations and counterfeit medications contributing substantially to adverse outcomes [6].

This paper synthesizes evidence from pharmacy literature, regulatory databases, and clinical case series to characterize the epidemiology, mechanisms, and clinical consequences of OTC medication complications with particular attention to the Indian context. We examine seven major drug categories: nonsteroidal anti-inflammatory drugs (NSAIDs), antihistamines, proton pump inhibitors, cough suppressants, laxatives, topical corticosteroids, and antacids. For each category, we delineate: (1) patterns of consumption and misuse; (2) pharmacological mechanisms predisposing to complications; (3) organ-system specific toxicity syndromes; (4) high-risk populations; and (5) evidence-based mitigation strategies.

1. Classification of OTC Drugs and Regulatory Context

OTC drug classification reflects a global consensus that certain therapeutic agents can be safely used with minimal professional oversight when directed appropriately. The American Pharmaceutical Association defines OTC drugs as agents that (1) present low toxicity potential;
(2) lack abuse liability; (3) require no monitoring parameters during use; (4) present low interaction potential; and (5) have straightforward therapeutic indications [9]. India's CDSCO Schedule classification incorporates these principles, yet categorization inconsistencies across state boundaries create regulatory arbitrage wherein products legally sold OTC in certain jurisdictions require prescription elsewhere.

Major OTC drug categories with significant complication potential include: (1) NSAIDs (ibuprofen, naproxen, diclofenac, indomethacin, nimesulide); (2) H1-receptor antagonists (diphenhydramine, cetirizine, fexofenadine); (3) antisecretory agents (omeprazole, ranitidine); (4) antitussives (dextromethorphan, codeine); (5) osmotic and stimulant laxatives (bisacodyl, senna);
(6) topical corticosteroids (betamethasone, clobetasol, hydrocortisone); and (7) antacids (aluminum hydroxide, calcium carbonate). The regulatory classification of these agents as OTC reflects historical precedent and political considerations as much as pharmacological evidence, creating systematic underestimation of complication risks [8].

India's OTC classification system operates under Schedule H1 and Schedule OTC categories. Schedule H1 medications include antimalarials, anticonvulsants, and selected corticosteroids, theoretically requiring pharmacist involvement at point of sale. Schedule OTC encompasses agents deemed safest, including acetaminophen, low-dose ibuprofen, simethicone, and first generation antihistamines. However, implementation varies substantially: surveys of 450 urban and 280 rural pharmacies across India documented that 58% of Schedule H1 products were dispensed without prescription, and 41% of Schedule OTC products were supplied with incorrect dosing information [7]. This regulatory slippage creates a de facto system wherein medication safety depends substantially on individual pharmacist knowledge and ethics rather than systematic oversight.

Table 1: Classification of Major OTC Drug Categories in India

Drug Class	Common Agents	Regulatory Status (India)	Primary Indication
NSAIDs	Ibuprofen, Diclofenac, Naproxen	Schedule OTC/H1	Pain, inflammation, fever
Antihistamines	Diphenhydramine, Cetirizine	Schedule OTC	Allergic rhinitis, urticaria
Antacids/PPIs	Omeprazole, Ranitidine	Schedule OTC/H1	Acid reflux, GERD
Antitussives	Dextromethorphan, Codeine	Schedule OTC/H1	Cough suppression
Laxatives	Bisacodyl, Senna	Schedule OTC	Constipation
Corticosteroids (Topical)	Clobetasol, Betamethasone	Schedule H1	Dermatitis, eczema

II. PATTERNS OF OTC DRUG CONSUMPTION AND MISUSE

Understanding the epidemiology of OTC medication use patterns forms the foundation for comprehending complication mechanisms and designing interventions. Indian pharmacy surveys demonstrate that approximately 65–72% of urban adult populations report OTC medication use within the preceding 12 months, compared to 45–50% in rural settings [6]. Within this population, NSAIDs represent the most frequently consumed category (estimated 42–48% of OTC users), followed by antihistamines (28–32%), antacids/PPIs (18–24%), and other categories [7].

Misuse patterns exhibit substantial heterogeneity by drug class. For NSAIDs, consumer surveys document that 35–42% of users exceed recommended daily doses, 28–35% use NSAIDs continuously for 14 days without medical evaluation, and 18–24% combine multiple NSAID formulations (including topical applications) simultaneously without recognition of cumulative exposure [3]. Antihistamine misuse involves 22–28% of users taking higher-than-recommended doses for sedative effects, 15–20% using first-generation agents long-term despite availability of safer alternatives, and 12–18% combining antihistamines with alcohol or central nervous system depressants [8].

Antacid consumption patterns demonstrate different risk profiles: approximately 45–52% of chronic antacid/PPI users employ these agents continuously for self-diagnosed reflux without medical assessment, 38–44% take inadequate doses, and 25–32% combine multiple antacid formulations. The Indian pharmaceutical market contains approximately 380 registered antacid/acidsuppression formulations, many combining multiple active ingredients, creating substantial risk for drug interactions and cumulative toxicity [38]. Laxative misuse appears particularly pronounced in India: epidemiological studies document that 28–35% of laxative users consume these agents 3 times weekly chronically, 18–24% escalate doses progressively due to tolerance development, and 8–12% combine multiple laxative classes simultaneously [25].

Demographic patterns reveal age-related consumption differences: adults aged 45–65 demonstrate the highest NSAID and antacid consumption, while middle-aged women (35–55) show greatest antihistamine use. Socioeconomic status inversely correlates with pharmacist consultation: lower-income consumers are 2.5–3.2 times more likely to use OTC medications without any healthcare professional guidance compared to higher-income counterparts [7].

III.PHARMACOLOGICAL MECHANISMS LINKING OTC DRUGS TO ORGANSPECIFIC COMPLICATIONS

a. Non-steroidal Anti-Inflammatory Drugs: Mechanistic Pathways to MultiOrgan Toxicity

NSAIDs exert therapeutic effects through competitive inhibition of cyclooxygenase (COX) enzymes, predominantly COX-1 and COX-2 isoforms, reducing prostaglandin and thromboxane synthesis. This mechanism confers analgesic, antipyretic, and anti-inflammatory efficacy but simultaneously eliminates critical homeostatic prostaglandin functions across multiple organ systems. COX-1-derived prostaglandins maintain gastric mucosal cytoprotection through PGE2 and PGI2, mediate renal hemodynamics via afferent arteriolar vasodilation, regulate platelet aggregation, and maintain vascular tone in systemic circulation.

Selective COX-2 inhibition, theoretically reducing GI toxicity while preserving anti- inflammatory efficacy, paradoxically increases cardiovascular thrombotic risk through unopposed TXA2 production by platelets and suppression of endothelial PGI2. NSAIDs of variable selectivity (from non- selective agents like ibuprofen to COX-2 selective inhibitors like celecoxib) produce heterogeneous organ toxicity patterns, yet all exhibit shared mechanisms of gastric mucosal injury, renal hemodynamic compromise, and cardiovascular prothrombotic effects [18].

b. Antihistamine-Mediated Toxicity: Anticholinergic Mechanisms

First-generation H1-receptor antagonists (diphenhydramine, chlorpheniramine, promethazine) possess substantial antimuscarinic properties supplementing histamine antagonism. These agents freely cross the blood-brain barrier, producing rapid sedation through central H1-receptor blockade but

simultaneously impairing central cholinergic neurotransmission critical for cognition, memory, and psychomotor function. Peripheral anticholinergic effects impair parasympathetic regulation of urinary tract motility, gastrointestinal propulsion, and intraocular pressure.

Second-generation agents (cetirizine, fexofenadine, loratadine) exhibit reduced blood-brain barrier penetration and minimal antimuscarinic properties, representing safer alternatives. However, Indian pharmaceutical marketing and consumer preference for rapid-onset sedation sustain first-generation antihistamine dominance in OTC markets, with first-generation agents constituting 68–74% of OTC antihistamine sales despite 30-year availability of superior alternatives [6].

3.1 Laxative-Induced Complications: Osmotic and Neural Mechanisms

Stimulant laxatives (bisacodyl, senna, picosulfate) induce colonic smooth muscle contraction through mechanisms involving local neuronal stimulation and direct smooth muscle effects. Chronic use precipitates tolerance development requiring progressive dose escalation, alongside pathophysiological changes including colonic smooth muscle atrophy, impaired neural function, and development of melanosis coli involving lipofuscin accumulation within colonic epithelial cells. Osmotic laxatives (polyethylene glycol, lactulose, sorbitol) retain water within colonic lumens, generating osmotic diarrhea. Chronic high-dose administration risks electrolyte abnormalities (hypokalemia, hyponatremia) and dehydration [10].

a. Antacid and Proton Pump Inhibitor Mechanisms

Antacids buffer gastric acid through neutralization (aluminum hydroxide, calcium carbonate) or reduced acid secretion (PPIs, H2-antagonists). Chronic antacid use impairs mineral ionization and absorption, reduces intrinsic factor-mediated B12 binding, and precipitates secondary hyperparathyroidism through hypocalcemia. PPIs irreversibly inhibit the gastric H+/K+-ATPase, suppressing acid secretion by 95%. While efficacious for reflux management, chronic PPI use impairs calcium and magnesium absorption, reduces bacterial clearance in the upper GI tract, and precipitates dysbiosis predisposing to pathogenic bacterial overgrowth [11].

b. Topical Corticosteroid Penetration and Systemic Absorption

Topical corticosteroids applied to skin undergo percutaneous absorption with bioavailability varying 0.1–1% for body surface areas to 30–45% for intertriginous and facial regions. Chronic application, particularly of high-potency agents (clobetasol 0.05%, betamethasone 0.1%) to sensitive body areas, generates systemic absorption sufficient to suppress the hypothalamic- pituitary-adrenal (HPA) axis, precipitate Cushing syndrome, and impair collagen synthesis [12].

IV. ORGAN-SYSTEM SPECIFIC COMPLICATIONS

4.1 Hepatic Toxicity Syndromes

i. NSAIDs and Liver Dysfunction

While NSAIDs rarely cause acute hepatotoxicity, chronic use produces subclinical elevations in transaminases in 1–3% of users. NSAIDs induce hepatic injury through mitochondrial dysfunction, oxidative stress generation, and altered lipid metabolism. A retrospective analysis of 1,247 cases presenting to tertiary care centers in India with NSAID-induced liver injury documented that 68% exhibited chronic exposure (12 weeks) at therapeutic doses, while only 32% presented with acute overdose-related patterns [13]. Risk factors include age 60 years (HR 2.8), pre-existing liver disease (HR 4.2), and concurrent use of hepatotoxic agents (HR 3.5).

ii. Antacid-Related Magnesium Depletion and Consequent Metabolic Effects

Chronic PPI and antacid use impairs magnesium absorption through mechanisms involving altered gastric pH and reduced mucosal transporter expression. Magnesium depletion precipitates hypomagnesemia (serum Mg 1.7 mg/dL) in 13–22% of chronic PPI users, with serious consequences including cardiac arrhythmias, muscle dysfunction, and impaired glucose homeostasis. A prospective study of 450 patients on chronic PPI therapy (median duration 3.2 years) documented hypomagnesemia in 56 patients (12.4%), with 11 patients (2.4%) experiencing symptomatic hypomagnesemia manifesting as tetany and arrhythmias [14].

4.2 Renal Complications

NSAIDs precipitate acute kidney injury through

renal hemodynamic mechanisms: suppression of renal prostaglandin synthesis reduces afferent arteriolar vasodilation, decreasing glomerular filtration pressure. This risk amplifies substantially in volume-depleted states, with concurrent ACE inhibitor/ARB therapy (synergistic hemodynamic effects), underlying chronic kidney disease (eGFR 60 mL/min), and advanced age. Indian studies examining 2,856 patients with CKD stage 3–4 on chronic NSAID therapy documented progression to ESRD (eGFR 15 mL/min) at annualized rates of 2.3% in NSAID users versus 0.6% in non-users, representing a 3.8-fold increased risk [15].

High-dose NSAIDs induce acute interstitial nephritis through direct tubular toxicity and immune-mediated mechanisms: retrospective analysis of 89 cases of NSAID-induced acute interstitial nephritis in Indian tertiary centers documented median serum creatinine elevation from
1.1 mg/dL to 4.2 mg/dL within 8.3 days of NSAID initiation, with 24% requiring dialysis and 8% progressing to chronic kidney disease despite NSAID discontinuation [16].

Laxative abuse chronically impairs renal function through dehydration and electrolyte wasting: a case series of 34 patients presenting with laxative abuse syndrome documented serum potassium 3.0 mEq/L in 76% (25/34), serum bicarbonate 30 mEq/L in 65% (22/34), and elevated serum creatinine (1.5 mg/dL) in 53% (18/34) [17].

4.3 Cardiovascular Complications
NSAIDs increase cardiovascular event risk through multiple mechanisms: suppression of endothelial PGI2 shifts the TXA2/PGI2 balance toward prothrombotic states; increased fluid retention and blood pressure elevation (particularly with indomethacin and diclofenac); and systemic inflammation amplification through altered eicosanoid metabolism. A meta-analysis of 30 cohort studies examining 247,000 NSAID users documented increased risk of acute myocardial infarction (RR 1.47, 95% CI 1.27–1.72), ischemic stroke (RR 1.38, 95% CI 1.15–1.67), and hemorrhagic stroke (RR 1.32, 95% CI 1.01–1.72) [20].

Data from Indian settings demonstrates amplified cardiovascular complications in populations with high baseline risk: a case-control study of 642 acute MI cases and 1,205 matched controls in three urban Indian centers found current NSAID use conferred OR 3.2 (95% CI 2.1– 4.8) for acute MI, with greater risk in participants with underlying hypertension (OR 4.8) or diabetes (OR 4.1) [21].

Decongestants and sympathomimetic compounds found in cough suppressant formulations increase blood pressure and precipitate arrhythmias: case reports document pseudoephedrine associated myocardial infarction, acute coronary syndrome, and sudden cardiac death, particularly in individuals with underlying coronary disease or uncontrolled hypertension [22].

4.4 Gastrointestinal Complications
NSAID-induced gastroduodenal ulceration and hemorrhage remain among the most frequent serious OTC drug-related complications globally. NSAIDs suppress PGE2 and PGI2-mediated mucosal cytoprotection, reduce mucus and bicarbonate secretion, and diminish mucosal blood flow. A meta-analysis incorporating 51 randomized controlled trials and observational cohorts documented that chronic NSAID use (3 times weekly, 12 weeks) increases upper GI bleeding risk from baseline 1–3 per 1000 users annually to 15–20 per 1000 annually, representing a 10–15 fold increase [18]. High-dose NSAIDs (e.g., ibuprofen 1200 mg daily, naproxen 500 mg daily) further amplify hemorrhage risk.

Indian studies demonstrate comparable or greater NSAID-related GI complications: an analysis of 897 patients presenting with upper GI bleeding to 15 tertiary care hospitals across India identified NSAID use in 42% of cases, with average hospital stay of 8.3 days, blood transfusions averaging 3.2 units, and in-hospital mortality of 4.2% [24]. Small bowel injury with videocapsule endoscopy detects ulcerations in 40–65% of chronic NSAID users, though most remain clinically asymptomatic [23].

Laxative abuse precipitates chronic diarrhea with associated malabsorption, protein-losing enteropathy, and hepatic encephalopathy in severe cases. Chronic stimulant laxative use induces colonic dysfunction characterized by markedly reduced muscular contractions and decreased mucosal nerve innervation density. Melanosis coli develops in nearly 100% of patients with 1 year of chronic stimulant laxative exposure, representing lipofuscin accumulation from enterocyte apoptosis and is

considered a marker of intestinal epithelial injury [10]. Antacid abuse produces constipation (aluminum hydroxide, calcium carbonate) or diarrhea (magnesium hydroxide) depending on formulation. Prolonged calcium carbonate use increases risk of milk-alkali syndrome (hypercalcemia, metabolic alkalosis, renal impairment) in 2–5% of chronic users, historically a major source of acute kidney injury before widespread PPI adoption [15].

4.5 Neurological Complications

First-generation antihistamines impair cognitive function through multiple mechanisms: central H1-receptor antagonism reduces histamine-mediated arousal; antimuscarinic effects suppress central cholinergic tone critical for memory and executive function; and these agents accumulate with chronic use, producing progressive cognitive dulling. A prospective cohort study of 2,156 older adults (aged 65 years) found cumulative anticholinergic medication burden (including OTC first-generation antihistamines) independently predicted incident cognitive impairment with dose response relationship: adjusted HR 1.23 for each additional anticholinergic medication, and 1.46 overall for highest versus lowest tertile of cumulative burden [27].

Dextromethorphan (DXM), present in numerous OTC cough suppressants, presents abuse potential with dissociative and hallucinogenic effects at supratherapeutic doses. Indian surveillance data documented 1,247 emergency department visits involving DXM toxicity during 2018–2022, with 89 cases progressing to severe dissociation and/or altered consciousness [26]. Chronic DXM abuse precipitates serotonin syndrome when combined with serotonergic agents, manifesting as agitation, hyperthermia, muscle rigidity, and autonomic instability

Table 2: Organ-System Toxicity Mapping: OTC Medications and Complication Profiles

Drug Class	Primary Target Organ	Mechanism of Injury	Incidence Rate (Annual)
NSAIDs	GI tract	Prostaglandin suppression, mucosal damage	15–20 per 1000 users
NSAIDs	Kidney	Hemodynamic compromise, AKI	4.2% in elderly
NSAIDs	Cardiovascular	Prothrombotic state, MI/stroke	RR 1.47–1.72
Antihistamines	CNS	Anticholinergic effects,cognitive decline	HR 1.46
Laxatives	Colon	Smooth muscle atrophy, dysbiosis	28–35% users
Antacids/PPIs	Renal	Electrolyte wasting, hypomagnesemia	12.4% users
Cough Suppressants	CNS	Dissociative effects, abuse	340% increase (2015-2022)
Topical Steroids	Systemic (HPA)	Percutaneous absorption, suppression	Varies by potency/area

V. DRUG–DRUG AND DRUG–DISEASE INTERACTIONS

OTC medications frequently interact with prescription medications and chronic disease processes, amplifying complication risk. NSAIDs combined with ACE inhibitors/ARBs create synergistic renal hemodynamic impairment: the combination increases acute kidney injury risk 5–8 fold compared to either agent alone. Additionally, NSAIDs inhibit the antihypertensive effect of ACE inhibitors/ARBs through suppression of renal prostaglandin-mediated sodium excretion and reduced renin release [19].

First-generation antihistamines combined with CNS depressants (alcohol, benzodiazepines, opioids) substantially increase sedation, impaired cognition, and fall risk in older adults. An Indian case-control study of 156 older adults with serious fall-related injuries found concurrent use of OTC antihistamines and CNS depressants present in 34% of cases versus

8% of non-injured controls (OR 6.2, 95% CI 3.1–12.4) [28].

Antacid/PPI interactions with other medications involve absorption impairment: PPIs increase gastric pH, reducing ionization and absorption of drugs requiring acidic environments (certain antibiotics, antifungals, iron supplements). A retrospective pharmacy database analysis of 45,000 patients on chronic PPI therapy documented 12.3% had concurrent iron supplementation, and among this subgroup, iron deficiency anemia developed in 28% despite ongoing supplementation, likely representing reduced bioavailability [11].

VI. OTC DRUG ABUSE AND DEPENDENCY SYNDROMES

Certain OTC medications exhibit abuse liability and can precipitate physical and psychological dependence. Laxative abuse represents a particularly important pattern: individuals with eating disorders frequently abuse laxatives to enhance weight loss. Indian studies of 340 female patients with bulimia nervosa and anorexia nervosa documented laxative abuse in 48%, with severe hypokalemia (K 2.5 mEq/L) in 22%, requiring hospitalization [25]. Laxative dependency develops through neuroadaptation: chronic stimulant laxative use leads to colonic smooth muscle desensitization and neural dysfunction, requiring progressively higher doses to achieve therapeutic effect. Discontinuation precipitates severe constipation and abdominal pain, creating powerful incentives for continued use.

Cough suppressant abuse involving dextromethorphan (DXM) has emerged as a significant public health concern, particularly among adolescents and young adults. DXM abuse patterns in India demonstrate rapid escalation from 2015–2022, with emergency department visits for DXM toxicity increasing 340% (from 68 cases in 2015 to 367 cases in 2022) [26]. DXM produces dose-dependent dissociative effects at 300–1500 mg (versus therapeutic doses of 10–30 mg), and chronic users develop psychological dependence characterized by compulsive use despite adverse consequences.

Antihistamine abuse occurs less frequently but demonstrates patterns of dependence in certain populations: individuals with pre-existing anxiety or insomnia disorders may escalate antihistamine doses for self-medication, developing tolerance requiring dose increases. Acute withdrawal following chronic high-dose use produces insomnia, anxiety, and irritability [27].

VII. SPECIAL POPULATION VULNERABILITIES

7.1 Elderly Patients

Older adults (aged 65 years) represent 25–30% of OTC medication users but experience 40–50% of serious adverse events. Age-related pharmacokinetic changes (reduced renal clearance, increased fat distribution, reduced albumin binding) amplify drug exposure and toxicity risk. Additionally, polypharmacy (concurrent use of 5 medications) increases 5-fold from ages 50–65 to 75 years, amplifying drug-drug interaction risks [27].

NSAIDs in elderly populations present particular risks: reduced renal perfusion pressure with aging (25–30% decline per decade after age 50) increases acute kidney injury risk 3–5 fold compared to younger adults. A cohort study of 8,942 participants aged 65 years taking NSAIDs documented incident acute kidney injury in 4.2% over 3 years of follow-up, concentrated among those with baseline eGFR 30–60 mL/min and/or concurrent ACE inhibitor/ARB use [21].

Anticholinergic medication sensitivity increases substantially in older age: anticholinergic burden predicts cognitive impairment, falls, urinary incontinence, constipation, and mortality with greater effect sizes in older compared to younger populations. Geriatric pharmacology guidelines recommend minimizing anticholinergic medications in older adults; first-generation antihistamines are flagged as potentially inappropriate medications in the Beers Criteria (American Geriatrics Society) due to dementia risk, sedation, and fall hazard [27].

7.2 Pregnant and Lactating Women

OTC medication use during pregnancy requires careful risk-benefit consideration: NSAIDs, particularly in third trimester, increase risk of premature ductus arteriosus closure (PDA) and oligohydramnios. Pregnancy-specific meta-analyses document that third-trimester NSAID exposure increases congenital heart defect risk (RR 1.63, 95% CI 1.17–2.27) and adverse renal outcomes. Therefore, NSAIDs should be avoided in pregnancy, particularly after 20 weeks gestation [32].

First-generation antihistamines possess teratogenic potential in animal studies, though human evidence remains limited. The FDA classifies diphenhydramine as Category B, indicating studies in animals do not show fetal risk, but no controlled human studies exist. Due to this uncertainty, first-generation antihistamines should be avoided in pregnancy; second-generation agents (loratadine, cetirizine) represent safer alternatives [31].

PPIs during pregnancy exhibit minimal teratogenicity: a meta-analysis of 8 prospective cohort studies involving 1,530 PPI-exposed pregnancies found no increased risk of major congenital anomalies, though some studies noted small increases in preterm birth [11].

Laxative use in pregnancy requires careful agent selection: stimulant laxatives may increase uterine contractions and precipitate premature labor; osmotic laxatives (polyethylene glycol, lactulose) are preferred. Anthraquinone laxatives (senna, aloe) generate concerns regarding potential increased miscarriage risk, though evidence remains conflicting [10].

Medication excretion into breast milk varies substantially: first-generation antihistamines achieve substantial milk concentrations with documented infant sedation and potential neurodevelopmental effects with chronic exposure; second-generation agents achieve minimal milk transfer. NSAIDs achieve low milk concentrations (1% of maternal dose) but occasional case reports document infant gastrointestinal symptoms [32].

7.3 Pediatric Populations

Pediatric patients present unique vulnerabilities: reduced metabolic capacity (particularly in infants 6 months), immature renal function, and difficulty communicating symptoms increase adverse event risk. NSAIDs in children precipitate severe renal injury more readily than in adults: acute kidney injury has been documented following therapeutic NSAID dosing in dehydrated children with gastroenteritis [29].

Dextromethorphan toxicity in children presents particular concern: case reports document life-threatening dissociation, seizures, and respiratory depression with accidental exposures or intentional abuse of high-dose cough suppressants. The American Academy of Paediatrics recommends against DXM use in children 6 years due to inefficacy and adverse event risk [30].

Topical corticosteroid absorption is amplified in children due to greater skin permeability (3–5 fold higher than adults) and higher surface area-to-body-weight ratio. Diaper occlusion enhances absorption 15–40 fold, creating substantial risk for HPA axis suppression and Cushing syndrome with high-potency topical corticosteroids applied to intertriginous regions [12].

Population	Age (years)	Complication Profile	Risk Elevation
Elderly patients	65	Renal injury, cognitive decline, falls	3–5 fold
Pregnant women	All	Fatal abnormalities, premature labour	Variable by drug
Lactating women	All	Infant CNS effects (antihistamines)	Variable by drug
Pediatric patients	18	Metabolic complications, toxicity	2–5 fold
CKD patients	All	AKI, progression to ESRD	3.8 fold (NSAIDs)
Patients with CVD	45+	MI, stroke, thrombotic events	1.5–3.2 fold

Table 3: High-Risk Populations and Associated OTC Medication Complications

VIII. REGULATORY FRAMEWORK AND GAPS: INDIA VERSUS GLOBAL STANDARDS

8.1 Indian OTC Regulatory Architecture

India's pharmaceutical regulatory framework derives

from the Drugs and Cosmetics Act (1940), formulated in the pre-antibiotic era and subsequently amended through the Drugs and Cosmetics Rules (1945, with multiple amendments through 2023). The Central Drugs Standard Control Organization (CDSCO) maintains the national regulatory authority, though state-level regulators implement policies with variable rigor.

The schedule classification system divides medications into categories: Schedule A/B (prescription-only, highly potent), Schedule C/C1 (restricted), Schedule D (restricted, manufacturing records required), Schedule X (psychotropic), Schedule Y (restricted new drugs), Schedule G (specified categories), and Schedule H1/OTC (available without prescription with varying retail oversight). This classification system exhibits critical limitations: decisions regarding OTC versus prescription classification frequently reflect historical precedent, pharmaceutical industry lobbying, and political considerations rather than contemporary pharmacological evidence [5].

Approximately 32% of OTC medications sold in India operate as unregistered formulations or products with incomplete efficacy/safety documentation, particularly in state markets and rural areas. The Central Drugs Standard Control Organization estimates that 25–35% of OTC products sold through unregulated channels (roadside vendors, local practitioners) contain substandard formulations, counterfeit agents, or contaminated materials [6].

8.2 Pharmacovigilance Infrastructure Deficiencies

India's pharmacovigilance system operates through the Adverse Events Following Immunization (AEFI) and more recently the Indian Pharmacopoeia Commission-operated Pharmacovigilance Programme of India (PvPI). However, PvPI focuses primarily on prescription medications and serious adverse events; OTC medication surveillance remains minimal. Estimates suggest that only 3–5% of actual ADRs occurring in Indian communities are captured by formal pharmacovigilance systems, compared to 10–15% in developed nations [2].

This surveillance gap creates substantial underestimation of OTC-related complications. Retrospective studies examining emergency department presentations in tertiary care centers document that OTC medications contribute to 12–18% of acute hospital admissions, yet most cases are not reported to pharmacovigilance authorities. A prospective study of 4,247 emergency department presentations in a New Delhi tertiary center identified OTC medication-related presentations in 589 cases (13.9%), yet pharmacovigilance reports were filed for only 45 cases (7.6%) [34].

8.3 International Regulatory Comparisons

Regulatory Parameter	India(CD- SCO)	USA (FDA)	Europe (EMA)	Australia (TGA)
Clinical trial requirement	Limited	Required	Required	Required
Postmarketing surveillance	Minimal	Mandatory	Mandatory	Mandatory
Packet size restrictions	None	Yes (some agents)	Yes	Yes
Pharmacovigilance reporting	5% ADRs captured	10–15% ADRs captured	12–18% ADRs captured	8–12% ADRs captured
Schedule re-evaluation period	None specified	5–10 years	5–10 years	5–10 years
Unregistered formulations	25–35% of market	1% of market	1% of market	1% of market

Table 4: Regulatory Comparison: OTC Medication Standards (India vs. International)

The United States FDA maintains more stringent OTC classification criteria: agents must demonstrate safety at proposed OTC doses through clinical trials, with ongoing pharmacovigilance postmarketing. Additionally, the FDA restricts packet sizes for certain agents (e.g., maximum 325 mg acetaminophen per dose, total 4 grams daily) to reduce unintentional overdose risk [4]. European Medicines Agency (EMA) similarly maintains higher evidentiary standards for OTC classification, with centralized registration of all OTC medications and continuous risk-benefit assessment [36].

Australia's Therapeutic Goods Administration (TGA) maintains particularly stringent standards: numerous agents available OTC in India (certain potent topical corticosteroids, dextromethorphan containing combination products) require prescription in Australia based on safety evidence [37]. Canada's regulatory system similarly restricts OTC availability relative to Indian standards, with Schedule H1 medications typically requiring prescription.

These international comparisons underscore that Indian OTC regulatory standards remain substantially less stringent than comparable developed nations. Risk-benefit re-evaluation incorporating contemporary safety evidence would likely necessitate reclassification of several commonly used OTC agents to prescription-only status.

8.4 Proposed Regulatory Enhancements

Evidence-based regulatory improvements for India include: (1) establishment of a dedicated OTC medication pharmacovigilance system capturing adverse events at community pharmacy and facility levels; (2) periodic (every 5–10 year) re-evaluation of OTC classifications based on updated safety evidence; (3) implementation of unique identifiers enabling tracking of medication batches for contamination/counterfeiting detection; (4) mandatory registration of all OTC formulations with CDSCO including full composition documentation; (5) standardized labeling requirements specifying contraindications, drug interactions, and maximum daily doses; and (6) establishment of OTC medication quality standards applicable uniformly across state boundaries [8].

IX. ROLE OF PHARMACISTS IN OTC MEDICATION RISK MITIGATION

Community pharmacists serve as the primary source of medication information for consumers in India, with 75–85% of OTC users consulting pharmacists regarding product selection. However, substantial heterogeneity exists in pharmacist knowledge, professional standards, and ethical practice. Studies assessing community pharmacist knowledge regarding OTC medication safety documented that 45–55% of pharmacists could correctly identify contraindications for NSAIDs, 38–48% understood major drug interactions, and only 25–35% provided counseling regarding maximum daily dose limits [7]. Evidence-based pharmacist interventions demonstrating effectiveness in reducing OTCrelated complications include: structured medication counseling (discussing indications, contraindications, dosing, drug interactions, and side effects), screening for contraindications before dispensing, detection of self-medication patterns suggesting abuse/dependence, and recommendation of alternative agents for high-risk populations. A randomized controlled trial involving 1,200 participants comparing standard OTC dispensing versus pharmacist-delivered structured counseling for NSAID users documented that pharmacist counseling reduced NSAID overuse (recommended daily doses) from 42% to 18%, and GI-related emergency department visits from 8.2 to 3.1 per 100 users annually [35].

Barriers to optimal pharmacist performance in OTC safety include: limited time availability (pharmacists in community settings average 3–5 minutes per customer transaction), insufficient training in contemporary pharmacology (particularly regarding drug interactions and special populations), economic pressures to maximize sales volume (pharmacist income often tied to dispensing volume), and limited oversight/accountability mechanisms [8].

Professional pharmacy organizations in India (Pharmacy Council of India, Association of Indian Pharmacists, All India Confederation of Pharmacists and Licensed Chemists) have undertaken initiatives to establish OTC medication counseling standards, develop training curricula, and promote professional ethics. However, implementation remains limited, with estimates suggesting only 15–25% of community pharmacies consistently implement structured OTC counseling protocols [6].

X. PUBLIC HEALTH IMPACT AND ECONOMIC BURDEN

OTC medication-related adverse events generate substantial healthcare costs and productivity losses. Estimates from health economic analyses conducted in India suggest that OTC-related ADRs precipitate direct healthcare costs (hospitalizations, emergency care, investigations) of approximately 8,000–12,000 crore Indian Rupees annually (USD 1.0–1.5 billion), with indirect costs from lost productivity exceeding

this amount [39].

Mortality from preventable OTC-related complications exceeds 8,000 deaths annually in India: NSAID-related GI hemorrhage mortality of 4,000–5,000 cases annually, antacid/PPI-related infection complications (Clostridioides difficile infections, other nosocomial infections) of 2,000–3,000 cases, and deaths from other drug-specific mechanisms constituting the remainder [34]. These estimates acknowledge substantial uncertainty due to incomplete reporting, but ordersof- magnitude estimates from tertiary care center analyses and poison control data support these ranges.

Economic burden by drug class: NSAIDs generate highest costs due to GI hemorrhage requiring hospitalization (average length of stay 6–8 days, costs 30,000–50,000 INR per admission); renal complications requiring dialysis initiation; and cardiovascular events (myocardial infarction, stroke) with long-term disability costs. Antacid/PPI complications center on infectious complications (nosocomial infections, C. difficile) with extended hospitalization. Laxative abuse predominantly generates psychiatric hospitalization costs and nutritional rehabilitation expenses in eating disorder populations [39].

XI. CASE-BASED CLINICAL OBSERVATIONS

The following anonymized cases illustrate typical OTC-related complication patterns encountered in Indian clinical practice:

Case 1: NSAID-Induced Hemorrhage in Elderly Patient
A 68-year-old male with hypertension (controlled with lisinopril) presented with melena and hemodynamic instability. History revealed chronic NSAID use (ibuprofen 1200 mg daily for 8 months) for osteoarthritis, obtained OTC without medical consultation. Laboratory studies: hemoglobin 6.8 g/dL, BUN 52 mg/dL, creatinine 3.2 mg/dL (baseline 1.1), platelet count 450,000/µL. Upper endoscopy revealed duodenal ulcer with visible vessel. Bleeding was controlled endoscopically; patient required 6 units packed red blood cells and 3-day ICU stay. Serum creatinine improved to 1.8 mg/dL with aggressive fluid resuscitation, but baseline renal function remained impaired. This case exemplifies NSAID complications in high-risk individuals: elderly age, ACE inhibitor use (synergistic hemodynamic effects), and chronic high-dose therapy.

Case 2: Dextromethorphan Toxicity in Adolescent
A 17-year-old male presented with altered consciousness, dissociation, and vertical nystagmus. Parents reported that patient obtained a cough suppressant formulation (containing dextromethorphan 10 mg/mL, 120 mL bottle) from a local pharmacy and consumed the entire bottle over 2 hours to achieve psychoactive effects. Serum DXM concentration: 2,840 ng/mL (therapeutic 75–250 ng/mL). Patient required 4 days hospitalization with benzodiazepines for sedation and airway monitoring; resolved without permanent sequelae. This case demonstrates DXM abuse potential and inadequate point-of-sale oversight in preventing high-dose purchases.

Case 3: Laxative Abuse Syndrome with Severe Electrolyte Abnormalities
A 32-year-old female with bulimia nervosa history presented with severe hypokalemia (K 2.1 mEq/L), hyponatremia (Na 128 mEq/L), and metabolic alkalosis (HCO3 42 mEq/L). Patient had been chronically using bisacodyl (3–5 tablets daily, total 15–25 mg) and senna (6–8 teaspoons daily equivalent to 432–576 mg) obtained OTC for 4 years. Abdominal examination revealed severe fecal loading and colonic dilation. Renal function was initially impaired (creatinine 2.1 mg/dL) but improved with aggressive electrolyte repletion and IV hydration. Patient required 5 days hospitalization and psychiatric intervention addressing eating disorder. This case illustrates severe colonic dysfunction and life-threatening electrolyte abnormalities from chronic laxative abuse.

Case 4: First-Generation Antihistamine-Related Fall and Fracture in Elderly Patient
A 72-year-old female with history of allergic rhinitis habitually used diphenhydramine 50 mg at bedtime (OTC) for sedative effect. After dinner, she took an additional 50 mg dose due to increased allergic symptoms. One hour later, she fell while ambulating to the bathroom, sustaining right femoral neck fracture. Orthopedic evaluation confirmed need for surgical fixation. This case exemplifies increased fall risk from high-dose first-generation antihistamines in elderly populations, compounded by underlying hip osteoporosis.

XII. ETHICAL AND LEGAL CONSIDERATIONS

OTC medication availability reflects implicit ethical judgments regarding individual autonomy versus paternalistic health protection. Unrestricted OTC access assumes adult consumers possess sufficient knowledge to use medications safely; however, empirical evidence demonstrates substantial gaps in consumer health literacy regarding medication safety, contraindications, and drug interactions. Indian studies assessing medication literacy documented that only 35–45% of adult OTC users understood maximum daily doses for common agents, 25–35% recognized major contraindications, and 20% understood drug interaction risks [7].

Legal liability for OTC medication-related complications remains incompletely defined in Indian jurisprudence. While healthcare providers (including pharmacists) have professional obligations to counsel appropriately and identify contraindications, enforcement mechanisms for OTCrelated negligence remain limited. The Consumer Protection Act (2019) provides mechanisms for pursuing claims against manufacturers for defective/unsafe products, but burden of proving product defect/inadequate warnings falls on plaintiffs, creating substantial barriers to successful litigation [33].

From an ethical standpoint, the principle of beneficence (maximizing benefits) must be balanced against respect for autonomy (allowing individuals to make self-directed medication choices). For medications with substantial abuse/dependence potential (laxatives, DXM), restricting OTC access to schedule-controlled status appears ethically justified given societal benefits of reduced harm exceed individual autonomy limitations. For agents with lower abuse potential but substantial interaction/contraindication risks (NSAIDs, first-generation antihistamines), enhanced counseling requirements and point-of-sale screening represent intermediate approaches balancing autonomy and safety [8].

Pharmaceutical industry incentive structures create ethical tensions: manufacturers benefit economically from broad OTC availability and minimal use restrictions. Industry-funded marketing campaigns frequently underrepresent risks, overstate benefits, and discourage professional oversight. This creates obligation for regulatory bodies and professional organizations to ensure independent, transparent communication of risk-benefit information to healthcare providers and consumers [6].

XIII.PREVENTIVE STRATEGIES AND POLICY RECOMMENDATIONS

13.1 Public Health Education

Population-level education regarding OTC medication safety should target multiple audiences: healthcare providers (physicians, nurses), community pharmacists, and the general public. Educational content should address: mechanisms of common adverse effects, recognition of contraindications, safe dosing limits, drug interaction risks, and appropriate circumstances for seeking professional medical consultation.Effective public health messaging avoids alarming language while clearly communicating risks

For example, rather than stating ”NSAIDs cause severe bleeding,” evidence-based messaging states ”NSAIDs increase risk of stomach bleeding in certain people, particularly those over 60 or taking blood thinners. Use the lowest dose for the shortest duration, and take with food or acid protection if possible.”

Media campaigns implemented in certain Indian states (notably Maharashtra and Gujarat) have demonstrated modest effectiveness: campaigns emphasizing the importance of pharmacist consultation for OTC NSAID use increased pharmacist consultation rates from 35–42% at baseline to 58–65% over 12 months, though sustained behavior change was limited [35].

a. Standardized Labeling and Packaging

Current OTC medication labeling in India frequently contains inadequate information regarding contraindications, drug interactions, maximum daily doses, and warning symptoms necessitating medical care. Standardized labeling requirements specifying these elements would enhance consumer understanding. Traffic light labeling systems (green for safe, yellow for caution/consult pharmacist, red for contraindications) represent practical implementations enhancing comprehension across literacy levels.

Packet size restrictions reduce unintentional overdose risk: limiting total ibuprofen per package to 1200 mg (12 tablets of 100 mg), or acetaminophen to 4 grams (16 tablets of 250 mg) would substantially reduce acute toxicity cases. Australia and some European nations employ such restrictions with documented effectiveness in reducing poisoning mortality [37].

b. Point-of-Sale Screening

Pharmacist-implemented screening protocols at OTC medication purchase identify contraindications and flag high-risk patients requiring additional counseling or professional referral. Screening algorithms addressing key contraindication categories include: age 65 years (requiring careful NSAID use), pregnancy status (contraindication for certain agents), concurrent medication use (identifying interaction risks), and underlying chronic conditions (liver disease, kidney disease, cardiovascular disease).

Electronic systems (integrated with pharmacy dispensing software) could facilitate rapid screening: when an OTC medication is selected, the system flags contraindications based on patient medication profile, age, and documented medical conditions. This approach has demonstrated effectiveness in reducing inappropriate medication use in pilot programs in urban Indian pharmacies [28].

c. Professional Continuing Education

Pharmacists require evidence-based continuing education regarding OTC medication safety, drug interactions, and appropriate counseling. Professional organizations (Pharmacy Council of India, state regulatory bodies) should mandate OTC safety training as component of continuing education requirements. Curriculum should address contemporary evidence regarding complication risks, mechanisms of toxicity, special population considerations, and evidence-based counseling techniques.

Physician education regarding OTC medication risks and interactions represents an oftenoverlooked intervention:

many patients present to physicians with OTC-related complications without mentioning OTC use, as patients do not perceive non-prescription medications as ”real drugs.” Physician education emphasizing the importance of OTC medication history during clinical assessment would enhance identification of OTC-related problems.

d. Regulatory Policy Changes

Policy recommendations include: (1) Establishment of OTC Medication Pharmacovigilance System: Dedicated surveillance capturing OTC-related ADRs at community pharmacy and facility levels, with mandatory reporting requirements. (2) Periodic Re-evaluation of OTC Classifications: Incorporation of emerging safety evidence into scheduling decisions, with explicit criteria for reclassification to prescription status if complication risk exceeds acceptable thresholds. (3) Standardized Labeling Requirements: Mandatory inclusion of contraindications, drug interactions, maximum daily doses, warning symptoms, and circumstances requiring medical consultation. (4) Packet Size Restrictions: Maximum allowable quantities per package for high-risk agents (NSAIDs, laxatives, DXM-containing products) to reduce unintentional overdose. (5) OTC Medication Counseling Standards: Establishment of minimum counseling requirements at point of sale, with documentation of counseling provided. (6) Quality Assurance Mechanisms: Inspection and certification programs ensuring OTC formulations meet pharmaceutical standards, with penalties for substandard/counterfeit products. (7) Decongestant and DXM-Containing Product Controls: Restriction of pseudoephedrine and DXM-containing products to prescription or restricted OTC status (e.g., sale limited to pharmacies with mandatory identification documentation).

XIV. LIMITATIONS OF CURRENT EVIDENCE AND KNOWLEDGE GAPS

This analysis incorporates available evidence from clinical studies, pharmacoepidemiological surveys, and regulatory data; however, substantial limitations merit acknowledgment. Pharmacovigilance Data Limitations: The 3–5% reporting rate for OTC-related ADRs in India creates substantial underestimation of true complication frequency. Case reports and series likely overrepresent severe complications, creating selection bias toward more dramatic presentations and potentially underestimating mild/moderate ADR frequency.

Geographical and Socioeconomic Heterogeneity: Most Indian evidence derives from urban tertiary care centers; rural and semi-urban complication patterns

remain incompletely characterized. Socioeconomic differences in OTC medication use patterns, access to healthcare, and complication outcomes remain inadequately studied.

Causality Attribution Challenges: Many OTC-related complications involve multifactorial etiology (e.g., NSAID-induced GI bleeding in patient with underlying ulcer disease and Helicobacter pylori infection); attribution of causality specifically to OTC medication versus other factors requires careful clinical judgment and remains subject to uncertainty.

Long-Term Outcome Data: Most studies characterize acute complications; long-term sequelae from chronic OTC use (e.g., progressive renal function decline, cognitive impairment development) remain inadequately documented.

Effectiveness Data for Interventions: While some pharmacist counseling studies demonstrate effectiveness in reducing OTC overuse, evidence regarding policy interventions (regulatory changes, labeling modifications, packet size restrictions) remains limited in Indian contexts.

XV. FUTURE DIRECTIONS

Future research and implementation directions include: (1) Population-Based Surveillance Systems: Development of enhanced pharmacovigilance capturing OTC-related ADRs with representative sampling across diverse Indian communities. (2) Mechanistic Studies: Further characterization of molecular mechanisms underlying OTC drug toxicity, identifying biomarkers for susceptibility and guiding personalized risk stratification. (3) Intervention Effectiveness Research: Randomized controlled trials of policy interventions (regulatory changes, labeling modifications, pharmacist counseling protocols) quantifying impact on adverse event reduction.

(4) Pharmacogenomic Research: Investigation of genetic variants predisposing to OTC-related complications (e.g., CYP2E1 polymorphisms influencing NAPQI formation and acetaminophen toxicity), enabling personalized dosing recommendations. (5) Digital Health Solutions: Development of mobile applications and pharmacy-integrated systems facilitating point-of-sale contraindication screening and counseling delivery. (6) Health Literacy Interventions: Evaluation of public health campaigns and educational strategies targeting OTC medication safety, with measurement of sustained behavior change. (7) Economic Evaluations: Comprehensive cost- effectiveness analyses of policy interventions, quantifying healthcare cost savings and productivity gains from adverse event reduction.

XVI. CONCLUSION

Over-the-counter medications provide essential public health benefits through enhanced therapeutic accessibility and reduced healthcare system burden. However, the current regulatory architecture and professional oversight mechanisms in India remain inadequate for optimal safety outcomes. OTC medications contribute substantially to preventable morbidity and mortality: estimates of 8,000 annual deaths and 12–18% of acute hospital admissions represent major public health impacts.

NSAIDs, despite therapeutic efficacy in pain management, precipitate serious gastrointestinal, renal, and cardiovascular complications at alarmingly high frequencies in Indian populations. First-generation antihistamines, while rarely causing severe acute toxicity, contribute substantially to cognitive impairment and falls in elderly populations. Laxative abuse generates life-threatening electrolyte abnormalities in vulnerable populations. Dextromethorphan-containing cough suppressants exhibit abuse potential inadequately addressed by current point-of-sale controls.

Mechanisms of OTC-related toxicity are well-characterized pharmacologically: NSAIDs suppress critical prostaglandin functions; antihistamines impair cholinergic neurotransmission; laxatives precipitate electrolyte wasting; antacids/PPIs impair nutrient absorption and alter gastrointestinal microbiota. Special populations (elderly, pregnant, pediatric) exhibit substantially amplified complication risk requiring tailored risk mitigation strategies.

India's regulatory framework for OTC medications, while providing general safety oversight, lacks the specificity and enforcement mechanisms present in comparable developed nations. Pharmacovigilance systems capture 5% of actual OTC-related ADRs, creating blind spots regarding emerging safety

signals. Community pharmacists, the primary source of medication consultation for OTC users, exhibit highly variable knowledge regarding safety and interactions; professional standards lack enforcement mechanisms.

Evidence-based policy interventions of demonstrated effectiveness include: structured pharmacist counseling (reducing NSAID overuse 42% to 18%); enhanced labeling with contraindications and interaction information; point-of-sale computerized screening; continuing professional education; and regulatory reclassification of high-risk agents. Implementation of comprehensive OTC safety improvements could reduce preventable complications by 35–45%, averting 3,000– 4,000 annual deaths and generating substantial healthcare cost savings.

The path forward requires multi-stakeholder engagement: regulatory bodies must strengthen pharmacovigilance and incorporate emerging evidence into scheduling decisions; professional organizations must establish and enforce counseling standards; healthcare providers must improve OTC medication history assessment; pharmaceutical manufacturers must ensure accurate, riskbalanced product information; and public health authorities must implement evidence-based education campaigns.

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