

Economic and Health Consequences of Unregulated Pharmaceutical Distribution in Assam: Examining Religious Patterns and the Path to Regulatory Reform

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ABSTRACT

Background: Unregulated over-the-counter (OTC) medication sales, particularly antibiotics and non-steroidal anti-inflammatory drugs (NSAIDs), represent a significant public health challenge in Assam, India. This study examines the relationship between unregulated pharmaceutical distribution, development of chronic diseases, associated financial burdens, demographic patterns in distribution networks, and pathways to regulatory reform.

Methods: We employed a multi-phase mixed-methods approach across 7 districts in Assam (January 2023-March 2024). Our innovative methodology integrated market surveillance (n=94), pharmaceutical tracing investigations (n=127), healthcare provider surveys (n=312), patient interviews (n=543), and in-depth case studies of 18 distribution networks. We employed social network analysis to map distribution pathways and developed sophisticated economic models to estimate financial impacts at household, healthcare system, and macroeconomic levels. This novel integration of pharmaceutical tracing, patient outcomes, and religious demographic analysis provides unprecedented insights into the organized nature of unregulated distribution networks.

Results: Unregulated medication sales demonstrated significant correlation with chronic disease prevalence ($r=0.74$, $p<0.001$) and catastrophic health expenditure incidence (OR 3.8, 95% CI: 2.9-4.7). Laboratory analysis of unregulated pharmaceuticals revealed 41.7% failed quality standards, with significant variation across medication categories (antibiotics: 53.2%, NSAIDs: 39.4%, corticosteroids: 68.7%). Distribution network analysis identified organized supply chains with 72.3% linked to specific religious affiliations. These operations resulted in estimated annual healthcare system costs of ₹1,297 crores (US\$171 million)—equivalent to 11.3% of Assam's total health budget—and pushed 11.4% of affected households below the poverty line.

Conclusions: Our findings document systematic circumvention of pharmaceutical regulations with specific religious demographic patterns, resulting in significant public health and economic consequences. We propose a three-phase implementation strategy beginning with a 6-month stakeholder engagement process, followed by 12-month regulatory infrastructure development, and culminating in coordinated cross-sector enforcement with technology-enabled monitoring. Urgent comprehensive regulatory reform focusing on pharmacovigilance, cross-sector enforcement, and accountability mechanisms is essential to address this "pharmacy terrorism" and protect public health.

Keywords- antimicrobial resistance; NSAIDs; chronic disease burden; economic impact; religious demographics; pharmaceutical regulation; Assam; health security; regulatory governance; health economics.

I. INTRODUCTION

The unregulated distribution and consumption of pharmaceuticals represents a critical public health challenge with far-reaching economic and social consequences. In the northeastern Indian state of Assam, preliminary evidence suggests widespread availability of prescription medications through unauthorized channels, with particular concerns regarding antibiotics and non-steroidal anti-inflammatory drugs (NSAIDs) (Baruah et al., 2021; Sharma & Goswami, 2022). These medications, when used inappropriately without proper medical supervision, can contribute to severe negative health outcomes including antimicrobial resistance (AMR) and chronic disease development (WHO, 2023).

1.1 Historical Context of Pharmaceutical Regulation in Assam

Assam's pharmaceutical regulatory landscape has evolved significantly since India's Drugs and Cosmetics Act of 1940. The state established its Drug Control Administration in 1956, but enforcement capacity has struggled to keep pace with the expanding pharmaceutical market. Until the 1990s, Assam maintained relatively effective control over pharmaceutical distribution through centralized supply chains. However, the liberalization of India's economy combined with Assam's complex geography and border dynamics created new challenges for regulatory oversight (Phukan & Devi, 2021). The introduction of the Drugs and Cosmetics (Amendment) Rules in 2006 and further amendments in 2017 attempted to strengthen regulatory frameworks, but implementation gaps have persisted, particularly in rural and semi-urban areas (Ministry of Health and Family Welfare, 2018).

1.2 Theoretical Framework

This research draws on theories of informal governance (Nordstrom, 2010), health market evolution in resource-constrained settings (Bloom et al., 2022), and regulatory capture frameworks (Carpenter & Moss, 2021) to understand how unregulated pharmaceutical distribution operates as a parallel health system with significant population health implications. We conceptualize unregulated pharmaceutical distribution not simply as regulatory non-compliance, but as an adaptive socioeconomic system operating at the intersection of market failures, governance gaps, and community networks.

The "infrastructural power" theory proposed by Mann (2018) helps explain how state capacity limitations create conditions for parallel governance systems to emerge, particularly in contexts with complex geographies and socio-political histories like Northeast India. Similarly, Hall and Deardorff's (2006) "lobbying as legislative subsidy" framework provides insight into how powerful market actors may strategically undermine regulatory enforcement through resource allocation influence.

From a public health perspective, we employ Farmer's (2004) concept of "structural violence" to understand how seemingly neutral market dynamics produce patterned health inequities that disproportionately affect marginalized populations. This framework helps explain why the health consequences of unregulated pharmaceutical distribution are not randomly distributed but follow predictable socioeconomic and demographic patterns.

1.3 Global Comparative Context

The challenges of unregulated pharmaceutical distribution are not unique to Assam, but comparative analysis suggests distinctive regional characteristics. Similar patterns have been documented in Bangladesh (Ahmed et al., 2023), Pakistan (Zaidi et al., 2021), and parts of Sub-Saharan Africa (Wafula et al., 2022). However, unlike contexts such as Bangladesh where distribution networks operate primarily through family connections, our preliminary investigations in Assam indicated community-based organization with religious institutions potentially serving as indirect facilitators of network development.

In Southeast Asian contexts such as Cambodia and Laos, unregulated pharmaceutical distribution has been linked primarily to border porosity and regulatory capacity limitations (Chuc et al., 2020). In contrast, Latin American studies have emphasized the role of pharmaceutical industry marketing practices in creating demand for inappropriate medication use (Homedes & Ugalde, 2021). The Assam context appears to combine elements of both patterns, with the added complexity of organized distribution networks potentially operating along community lines.

1.4 Research Objectives

Recent investigations have indicated potential demographic patterns in the organization of unauthorized pharmaceutical distribution networks in the region (Rahman et al., 2023). However, comprehensive analysis of the relationships between these distribution networks, specific health outcomes, economic impacts, and demographic factors has been lacking. Understanding these relationships is essential for developing targeted regulatory and public health interventions.

The present study addresses this critical gap by examining:

1. The relationship between unauthorized pharmaceutical sales and the development of specific chronic health conditions
2. Economic impacts of resulting chronic diseases at household, healthcare system, and macroeconomic levels
3. Structural and demographic characteristics of unregulated pharmaceutical distribution networks
4. Regulatory failures enabling systematic circumvention of pharmaceutical governance
5. Evidence-based pathways to comprehensive regulatory reform and health system strengthening

By establishing these relationships, this research aims to provide an evidence base for urgent regulatory reform and public health intervention in Assam and similar contexts.

II. MATERIALS AND METHODS

2.1 Study Design

We implemented a sequential mixed-methods study with five integrated components: (1) market surveillance, (2) pharmaceutical supply chain investigation, (3) healthcare provider survey, (4) patient cohort study, and (5) economic impact analysis. This integrated methodological approach enables a comprehensive examination of both the extent and consequences of unregulated pharmaceutical distribution.

2.2 Setting and Sampling

Research was conducted across seven districts of Assam selected through stratified random sampling to represent diverse geographic, economic, and demographic characteristics. Districts were stratified by healthcare access indices, urbanization levels, and religious demographic composition based on census data.

Table 4: provides detailed characteristics of the selected districts:

District	Population	Urban %	Healthcare Access Index	Religious Demographics (%)	Market Sites Sampled
District A	2,174,865	23.7	0.67	Religion A: 57.3, B: 32.5, C: 10.2	17
District B	1,835,421	19.2	0.52	Religion A: 43.1, B: 41.6, C: 15.3	14
District C	2,507,632	31.5	0.75	Religion A: 62.7, B: 27.8, C: 9.5	16
District D	1,342,786	12.8	0.48	Religion A: 38.2, B: 51.4, C: 10.4	12
District E	1,921,453	26.3	0.61	Religion A: 51.7, B: 36.9, C: 11.4	15
District F	1,587,294	15.7	0.39	Religion A: 29.6, B: 59.3, C: 11.1	11
District G	1,742,508	28.1	0.72	Religion A: 64.2, B: 25.1, C: 10.7	14

2.3 Sample Size Calculation and Power Analysis

Sample sizes for each component were determined through appropriate statistical power analyses. For market surveillance, we calculated that 94 sites would provide 80% power to detect a 15% difference in regulatory non-compliance rates between different market types with 95% confidence. For the patient cohort, 543 participants provided 90% power to detect an odds ratio of 1.5 for the association between unauthorized medication use and chronic disease development, assuming a baseline prevalence of 20% and accounting for potential confounding variables.

2.4 Data Collection

2.4.1 Market Surveillance

We conducted systematic audits at 94 pharmaceutical sales points, including weekly markets (n=47), permanent unregistered vendors (n=32), and

registered pharmacies serving as controls (n=15). Trained researchers documented:

- Types and quantities of medications available
- Pricing structures
- Regulatory compliance indicators (presence of Drug License numbers, GST registration, qualified pharmacist)
- Vendor demographic characteristics
- Product sourcing declarations
- Dispensing practices

Market surveillance data was collected using tablet-based structured observation forms developed in REDCap, validated through pilot testing at 8 sites not included in the final sample. Inter-rater reliability was established through duplicate observations at 15% of sites, achieving a Cohen's kappa of 0.87 for key regulatory compliance indicators.

2.4.2 Pharmaceutical Tracing Investigation

For a subset of medications (n=127) obtained through market surveillance, we conducted:

- Laboratory analysis of pharmaceutical composition and quality
- Authentication verification with purported manufacturers
- Supply chain tracing using batch numbers and packaging analysis
- Comparison of labeling information with regulatory databases

This component involved collaboration with the State Drug Testing Laboratory and pharmaceutical forensics experts. Quality assessment followed Indian Pharmacopoeia (2022) standards, including assays for active pharmaceutical ingredient (API) content, dissolution profiles, and contaminant identification using high-performance liquid chromatography (HPLC) and mass spectrometry.

Quality standards were categorized as:

1. Meeting all pharmacopeias standards
2. Minor deviation (80-99% of specified API content, acceptable dissolution)
3. Major deviation (60-79% of specified API content or unacceptable dissolution)
4. Critical failure (<60% of specified API content, contamination, or both)

2.4.3 Healthcare Provider Survey

We surveyed 312 healthcare providers (physicians n=176, pharmacists n=87, community health workers n=49) regarding:

- Observed patterns of medication misuse
- Frequency of encountering complications attributable to unregulated medications
- Chronic disease presentations potentially linked to inappropriate medication use
- Perceptions of regulatory effectiveness
- Recommendations for intervention

The healthcare provider survey instrument underwent rigorous validation including cognitive

testing with 17 participants, test-retest reliability assessment ($r=0.89$), and expert panel review by 6 specialists in pharmaceutical policy, health economics, and medical anthropology.

2.4.4 Patient Cohort Study

We conducted structured interviews with 543 patients diagnosed with chronic conditions potentially attributable to inappropriate medication use:

- Chronic kidney disease ($n=127$)
- Gastric ulceration and bleeding ($n=143$)
- Cardiovascular complications ($n=89$)
- Chronic liver disease ($n=64$)
- Antimicrobial-resistant infections ($n=120$)

Interviews explored medication use history, purchasing patterns, economic impacts, and healthcare-seeking behaviors. Medical records were reviewed with patient consent to establish potential causal relationships between medication use and disease development. We employed a validated medication history tool adapted from Patel et al. (2019) that included visual identification of medications, time-location mapping of purchase patterns, and cross-verification with available prescription records.

Case-control matching for a subset of 212 patient-pairs allowed for stronger causal inference, controlling for age (± 3 years), sex, district of residence, baseline socioeconomic status, and pre-existing comorbidities.

2.4.5 Economic Impact Analysis

We developed economic models to estimate:

- Direct healthcare costs attributable to complications of inappropriate medication use
- Indirect costs including lost productivity and caregiver burden
- Catastrophic health expenditure incidence
- System-level impacts on public healthcare infrastructure
- Macroeconomic implications including labor market effects and tax revenue impacts

The analysis integrated data from patient interviews, healthcare facility records, and state health accounts. We employed the following economic modeling approaches:

1. Cost-of-illness analysis using both human capital and friction cost approaches
2. Catastrophic health expenditure calculation following WHO methodology (household healthcare expenditure $>40\%$ of non-food expenditure)
3. System impact modeling using healthcare resource group analysis
4. Macroeconomic projection using a calibrated computable general equilibrium model

The economic modeling methodology is represented by the following equation for total economic cost:

$$TEC = \sum_{i=1}^n (DC_i + IC_i + FC_i) \times PAF_i$$

Where:

- TEC = Total Economic Cost
- DC = Direct Medical Costs
- IC = Indirect Costs (productivity loss)
- FC = Family/Caregiver Costs
- PAF = Population Attributable Fraction for unauthorized medication
- i = Disease category

2.5 Religious Demographic Data Collection

At all study phases, demographic data including religious affiliation was collected following ethical guidelines for sensitive demographic information. This data collection was justified by preliminary evidence suggesting organized distribution networks potentially operating along community lines (Rahman et al., 2023). To prevent stigmatization, results are presented using non-specific religious categorization (Religion A, B, C) rather than specific religious identifiers.

Religious affiliation data was collected through self-identification using categories from the Indian Census, with additional subcategories to capture the heterogeneity within major religious groups in the region. Trained interviewers from diverse backgrounds conducted data collection to minimize potential response bias.

2.6 Social Network Analysis Methodology

To understand the structure and organization of distribution networks, we employed social network analysis (SNA) methodology. This approach allowed us to:

1. Map the connections between different actors in the supply chain
2. Identify key nodes and gatekeepers within networks
3. Analyze network density and centralization characteristics
4. Examine homophily patterns along demographic lines

Data for SNA was collected through a combination of:

- Pharmaceutical tracing (identifying connections between distributors)
- Key informant interviews with regulatory officials and market actors
- Documented financial transactions where available
- Geographic clustering analysis

Network visualization and metrics were generated using Gephi 0.9.7, with key metrics including:

- Degree centrality (number of connections)
- Betweenness centrality (gatekeeping potential)
- Network density (proportion of possible connections that exist)
- Modularity (community structure within networks)
- Homophily indices for religious affiliation

2.7 Data Analysis

Quantitative data were analyzed using STATA 17.0. Chi-square tests assessed relationships between categorical variables, and multivariate regression models examined relationships between medication sources,

chronic disease development, and economic outcomes while controlling for confounding factors.

Logistic regression models included the following covariates:

- Age (continuous)
- Sex (categorical)
- Socioeconomic status quintile (ordinal)
- Educational attainment (ordinal)
- District of residence (categorical)
- Baseline health status (composite score)
- Healthcare access index (continuous)
- Religious affiliation (categorical)

For geospatial analyses, we employed ArcGIS 10.8 to map distribution patterns, disease clusters, and relationships with demographic variables. Spatial autocorrelation was assessed using Global Moran's I statistic, with hot spot analysis conducted using Getis-Ord Gi*.

Qualitative data underwent thematic analysis using NVivo 14, with coding conducted independently by two researchers (inter-coder reliability $\kappa=0.83$). The coding framework was developed through an iterative process combining deductive codes from the research questions and inductive codes emerging from the data.

Supply chain analysis employed social network analysis methodology using Gephi 0.9.7 to visualize and quantify distribution network characteristics.

2.8 Ethical Considerations

The study received ethical approval from the Institutional Ethical Committee of Manipur International University, Imphal, Manipur (Reference: MIU/IEC/2022/06). Informed consent was obtained from all participants. To prevent stigmatization, specific religious identities are anonymized in reporting. Data security protocols were implemented to protect sensitive information.

Additional ethical safeguards included:

- Community advisory board review of research protocols
- Regular ethical monitoring throughout data collection
- Secure data management with encryption and restricted access
- Debriefing with affected communities prior to publication
- Commitment to data sharing with health authorities to inform intervention

III. RESULTS

3.1 Prevalence and Characteristics of Unregulated Pharmaceutical Sales

Market surveillance identified widespread availability of prescription medications through unauthorized channels. Table 1 presents the prevalence of different medication categories available without prescription and without regulatory compliance.

Table 1: Prevalence of Unauthorized Pharmaceutical Sales by Category

Medication Category	Overall Availability (%)	Without Prescription (%)	Without Drug License (%)	Without GST Registration (%)
Antibiotics	87.3	91.4	83.6	89.7
NSAIDs	94.6	97.8	86.2	92.3
Corticosteroids	62.1	79.3	89.1	94.8
Antihypertensives	52.7	76.5	84.3	93.1
Hypoglycemics	49.2	72.8	81.9	90.4
Opioid analgesics	38.5	89.7	94.2	98.6

Urban-rural comparison revealed significant disparities, with rural areas having higher prevalence of unauthorized sales across all medication categories (mean difference 13.7%, $p<0.001$). Temporal analysis showed peak availability during weekly market days, with 27.3% higher medication availability compared to non-market days ($p<0.001$).

Laboratory analysis of samples revealed significant quality concerns:

- 41.7% failed to meet pharmacopeial standards for active ingredient content
- 27.3% contained detectable contaminants
- 18.9% showed evidence of improper storage affecting stability
- 52.6% had packaging inconsistent with manufacturer specifications

Quality failure rates varied significantly by medication category ($\chi^2=37.2$, $p<0.001$), with antibiotics (53.2%), corticosteroids (68.7%), and opioid analgesics (72.1%) showing the highest failure rates. NSAIDs demonstrated a lower but still concerning failure rate of 39.4%.

Pricing analysis revealed that unregulated pharmaceuticals were sold at an average of 43.2% below registered pharmacy prices (95% CI: 38.7-47.9%), creating a significant economic incentive for consumers, particularly those from lower socioeconomic groups.

3.2 Chronic Disease Development and Economic Impact

Analysis of patient data revealed significant associations between unauthorized medication use and chronic disease development (Table 2).

Table 2: Association Between Unauthorized Medication Use and Chronic Disease Development

Disease Category	Prevalence in Study Population (%)	Attributable to Unauthorized Medication Use (%)	Adjusted Odds Ratio (95% CI)*
Chronic kidney disease	23.4	62.7	4.7 (3.8-5.6)
Gastric complications	26.3	78.3	5.9 (4.7-7.1)
Cardiovascular complications	16.4	47.2	3.1 (2.4-3.8)
Chronic liver disease	11.8	53.6	3.8 (2.9-4.7)
AMR infections	22.1	81.4	6.3 (5.2-7.4)

*Adjusted for age, sex, socioeconomic status, comorbidities, healthcare access, district of residence, and educational attainment

In the case-control analysis, patients with histories of unauthorized medication use had significantly higher odds of chronic disease development (OR 4.8, 95% CI: 3.9-5.9) compared to their matched controls, after adjusting for confounding variables.

The causality assessment based on Bradford Hill criteria revealed strong temporal relationships between unauthorized medication use and disease development, with dose-response relationships evident in 73.6% of cases. Medication-specific attribution analysis identified NSAIDs as the primary contributor to chronic kidney disease and gastric complications, while antibiotics were most strongly associated with AMR infections and certain hypoglycemics with liver disease.

Intersectional analysis examining the interaction between religious affiliation, socioeconomic status, and urban/rural location found that the relationship between religion and chronic disease outcomes was significantly moderated by socioeconomic status (interaction term $\beta=0.42$, $p<0.01$) and healthcare access (interaction term $\beta=0.37$, $p<0.01$).

3.2.1 Economic Burden at Multiple Levels

The economic analysis revealed substantial financial burdens at household, healthcare system, and macroeconomic levels:

Household-level impacts:

- Mean out-of-pocket expenditure for treatment of resulting chronic conditions: ₹47,823 annually (US\$632)
- Proportion of households experiencing catastrophic health expenditure (>40% of non-food expenditure): 39.7%
- Proportion of affected households pushed below poverty line: 11.4%
- Mean lost workdays due to illness: 47.3 days annually
- Proportion of patients reporting job loss due to illness: 23.8%
- Mean reduction in household income attributable to condition: 31.7% (95% CI: 27.3-36.1%)
- Average debt incurred for medical treatment: ₹78,432 (US\$1,037)
- Proportion selling productive assets to finance care: 27.3%

The household economic impact showed substantial socioeconomic gradients, with households in the lowest wealth quintile experiencing 3.2 times higher rates of catastrophic health expenditure compared to those in the highest quintile (95% CI: 2.7-3.8).

System-level impacts:

- Estimated annual cost to Assam healthcare system: ₹1,297 crores (US\$171 million)
- Proportion of tertiary hospital beds occupied by patients with conditions attributable to unauthorized medication use: 17.3%
- Estimated increase in healthcare workforce requirements: 2,143 additional healthcare professionals
- Annual pharmaceutical expenditure for treatment of resulting conditions: ₹493 crores (US\$65.1 million)
- Diagnostic services cost burden: ₹217 crores (US\$28.7 million)

- Emergency service utilization attributable to complications: 23.7% of capacity

The system-level costs represent 11.3% of Assam's total health budget, significantly constraining resources available for preventive care and health system strengthening.

Macroeconomic impacts:

- Estimated annual productivity loss: ₹2,782 crores (US\$367.4 million)
- Total economic burden (direct + indirect costs): ₹4,079 crores (US\$538.4 million)
- Equivalent to 2.1% of Assam's Gross State Domestic Product
- Estimated annual tax revenue loss: ₹163 crores (US\$21.5 million)
- Projected 5-year cumulative economic impact: ₹23,971 crores (US\$3.16 billion)

The computable general equilibrium model projects that addressing unregulated pharmaceutical distribution would increase Assam's annual economic growth rate by 0.37 percentage points over a 5-year period.

3.3 Religious Demographic Patterns in Distribution Networks

Analysis of distribution networks revealed significant patterns along religious demographic lines.

Key findings include:

- 72.3% of identified distribution networks demonstrated homogeneous religious affiliation throughout the supply chain
- Religion A was significantly overrepresented in distribution network leadership (OR 5.7, 95% CI: 4.8-6.6)
- 83.2% of relabeling operations identified were affiliated with Religion A organizations
- Geographic clustering of unauthorized vendors showed significant correlation with religious demographic distribution ($r=0.71$, $p<0.001$)
- Network density was significantly higher within homogeneous religious networks (0.67) compared to heterogeneous networks (0.31, $p<0.001$)
- Mean path length within networks was 2.7 nodes, indicating relatively direct supply chains
- Betweenness centrality analysis identified key gatekeepers, 78.6% of whom shared religious affiliation with their primary distribution partners

When examining the interaction between religious affiliation, socioeconomic status, and urban/rural location, we found that the relationship between religion and distribution network participation was moderated significantly by economic opportunity index scores (interaction term $\beta=0.37$, $p<0.01$).

Comparing our findings with similar challenges documented in Bangladesh (Ahmed et al., 2023), we observed that distribution networks in Assam operate primarily through community-based organization rather

than family connections, with religious institutions often serving as indirect facilitators of network development. Qualitative analysis of key informant interviews corroborated these findings:

"These operations are tightly organized along community lines. Suppliers from [Religion A] distribute primarily through vendors from the same community. There's a clear hierarchical structure with centralized sourcing and distributed retail." (Regulatory official, District C)

"The medications come from outside Assam, primarily from [neighboring state]. They're brought in bulk, relabeled in small operations, and then distributed through community networks. The labeling often includes counterfeit Drug License numbers or none at all." (Healthcare provider, District A)

"There's a strong trust element in these networks. People prefer to work with those from the same community background because it reduces risks in what they know is technically illegal business. The religious centers sometimes provide a meeting place, though usually not directly involved in transactions." (Anonymous vendor, District E)

Gender analysis revealed that while men dominated wholesale and transportation roles (87.3%), women constituted a significant proportion of retail vendors (43.7%), particularly in weekly markets. This gender distribution showed significant variation across religious groups, with Religion C having the highest proportion of female vendors (58.2%) compared to Religion A (37.4%) and Religion B (42.1%).

3.4 Characteristics of Illicit Pharmaceutical Operations

Investigation identified systematic regulatory evasion strategies employed by unauthorized pharmaceutical operations:

Table 3: Regulatory Evasion Strategies in Unauthorized Pharmaceutical Operations

Evasion Strategy	Prevalence (%)	Associated with Religion A (%)	Associated with Religion B (%)	Associated with Religion C (%)
Medication relabeling	67.4	83.7	12.3	4.0
Absent/counterfeit DL number	83.6	79.1	14.5	6.4
GST non-compliance	91.2	77.6	15.3	7.1
Interstate sourcing	76.8	84.2	11.7	4.1
Mobile operations	62.3	71.9	17.8	10.3
Community-specific distribution	58.7	68.3	19.2	12.5

Geographic analysis revealed that 73.2% of unauthorized pharmaceutical products originated from three neighboring states, with consistent supply routes through specific border transit points. Cross-border movement patterns showed temporal correlation with weekly markets ($r=0.78$, $p<0.001$).

Temporal analysis of market surveillance data revealed systematic patterns of operation, with peak distribution activity occurring 2-3 days before weekly markets, suggesting coordinated supply chains rather than opportunistic sales.

Documentation of specific chronic diseases resulting from inappropriate medication use revealed several common patterns:

1. Chronic kidney disease: Primarily associated with long-term NSAID use (73.2%) and aminoglycoside antibiotics (24.6%)
2. Gastric complications: Strongly associated with non-prescribed NSAID use (89.7%), particularly diclofenac (47.3%) and ketorolac (26.8%)
3. Cardiovascular complications: Associated with certain COX-2 inhibitors (51.2%) and corticosteroid misuse (37.5%)
4. Chronic liver disease: Associated with inappropriate antituberculosis medication (42.7%), unauthorized antiretroviral therapy (21.6%), and hepatotoxic drug combinations (35.7%)
5. AMR infections: Strongly correlated with incomplete antibiotic courses (78.3%), inappropriate antibiotic selection (64.7%), and substandard medication quality (57.2%)

3.5 Consumer Behavior and Demand-Side Factors

Analysis of patient interview data revealed important insights into factors driving consumer participation in unauthorized pharmaceutical markets:

Table 5: Factors Influencing Consumer Use of Unauthorized Pharmaceutical Sources

Factor	Importance Rating (1-5)	Prevalence Among Users (%)	Urban vs. Rural Difference
Cost savings	4.7	91.3	Urban: 4.5, Rural: 4.8 (p<0.05)
Convenience/proximity	4.2	84.7	Urban: 3.9, Rural: 4.5 (p<0.01)
Absence of prescription requirement	3.9	76.2	Urban: 3.7, Rural: 4.0 (NS)
Perceived effectiveness	3.6	67.8	Urban: 3.4, Rural: 3.7 (NS)
Trust in vendor	3.5	59.3	Urban: 2.9, Rural: 3.8 (p<0.001)
Recommendation from social network	3.3	62.7	Urban: 2.8, Rural: 3.6 (p<0.001)
Lack of formal healthcare access	3.1	53.2	Urban: 2.3, Rural: 3.7 (p<0.001)

Socioeconomic analysis revealed that while cost was the primary driver across all income quintiles, the relative importance of healthcare access limitations was significantly higher for lower-income households ($\beta=0.47$, $p<0.001$).

Qualitative analysis identified additional demand-side factors:

1. Low health literacy: Limited understanding of medication risks and proper usage
2. Previous negative experiences with formal healthcare systems
3. Time constraints preventing formal healthcare utilization
4. Cultural familiarity with traditional medicine vendors transitioning to pharmaceutical sales
5. Perception of similar effectiveness between regulated and unregulated sources

Patient knowledge assessment revealed that only 23.7% of respondents could correctly identify potential risks associated with NSAIDs, and just 31.4% understood the concept of antibiotic resistance. This knowledge gap was significantly associated with educational attainment ($r=0.67$, $p<0.001$) and urban residence ($r=0.43$, $p<0.001$).

3.6 Regulatory Capacity and Enforcement Gaps

Analysis of regulatory systems identified critical capacity limitations:

1. Insufficient inspection resources: One drug inspector per 467 registered pharmaceutical outlets (WHO recommendation: 1:100)
2. Laboratory capacity constraints: Average 73-day backlog for quality testing
3. Jurisdictional fragmentation: Overlapping authority between agencies with limited coordination
4. Enforcement penalties: Average fine for non-compliance (₹7,500) represents only 4.3% of estimated monthly profit from unauthorized operations
5. Technology limitations: Manual record-keeping systems with limited cross-verification capabilities
6. Border control challenges: Only 3 of 12 major interstate checkpoints had pharmaceutical inspection capacity

Stakeholder interviews with regulatory officials revealed several systemic challenges:

"We simply don't have the manpower to conduct regular inspections, especially in rural areas. With the current staffing, each registered outlet might be inspected once every two years, while unregistered operations can essentially operate without oversight." (State Drug Controller Office, Senior Official)

"Even when violations are detected, the legal process is so cumbersome that prosecution is rarely completed. Cases often remain pending for years, during which time operations continue." (Legal Officer, Regulatory Affairs)

"There's a fundamental mismatch between the scale of the problem and the resources allocated to address it. When you compare our budget to the estimated size of the unregulated market, we're trying to control a flood with a paper cup." (District Drug Inspector)

IV. DISCUSSION

4.1 The Public Health Security Threat of Unregulated Pharmaceutical Distribution

Our findings document widespread and organized distribution of unregulated pharmaceuticals in Assam with severe public health consequences. The strong association between unauthorized medication access and chronic disease development represents a significant threat to population health with substantial economic implications. The characterization of these practices as "pharmacy terrorism" is supported by our

findings demonstrating systematic circumvention of pharmaceutical safety regulations resulting in population-level harm.

Drawing on Davies' (2008) concept of "health security," we argue that unregulated pharmaceutical distribution constitutes a non-traditional security threat through multiple pathways:

1. Direct health harms to individuals through improper medication selection and quality issues
2. Population-level threats through antimicrobial resistance development
3. Health system undermining through increased burden of preventable disease
4. Economic security impacts through productivity loss and healthcare costs
5. Social cohesion risks when distribution patterns follow demographic lines

Of particular concern is the high prevalence of quality failures among sampled medications. The combination of inappropriate medication selection, dispensing without proper guidance, and substandard pharmaceutical quality creates multiple pathways to adverse health outcomes. This is especially apparent in the development of antimicrobial resistance, where our findings align with growing evidence that unregulated antibiotic access represents one of the most significant drivers of AMR globally (WHO, 2023).

The economic analysis demonstrates how these practices create substantial financial burdens at both household and system levels. The finding that 11.4% of affected households were pushed below the poverty line highlights how unauthorized pharmaceutical distribution contributes to cycles of poverty and ill health, consistent with financial protection literature emphasizing the two-way relationship between health shocks and economic vulnerability (Kruk et al., 2022). At the system level, the estimated annual cost of ₹1,297 crores represents resources that could otherwise be directed toward strengthening primary healthcare infrastructure and preventive services.

4.2 Religious Demographic Patterns and Network Structures

The significant correlation between religious affiliation and pharmaceutical distribution network participation requires careful interpretation. While our findings clearly document organized distribution systems operating along religious community lines, these patterns should be understood within broader socioeconomic and historical contexts rather than essentialized religious characteristics.

Unlike similar challenges documented in Bangladesh (Ahmed et al., 2023) where distribution networks operate primarily through family connections, our findings demonstrate community-based organization with religious institutions often serving as indirect facilitators of network development. This pattern shows important parallels with other informal economy sectors in Northeast India, where community-based trade

networks have developed in response to formal market access limitations (Bhattacharya, 2021).

Several factors may contribute to these observed patterns:

1. **Pre-existing trade networks:** Communities with established interstate commercial relationships may leverage these networks for pharmaceutical distribution. Historical analysis by Sangwan (2022) demonstrates how certain religious communities in Assam developed interstate trade connections as adaptive responses to economic marginalization in the post-colonial period.
2. **Social capital utilization:** Close-knit religious communities may provide the trust and social cohesion necessary for operating outside regulatory frameworks. As Putnam's (2020) social capital theory suggests, religious organizations often generate high levels of bonding capital that can facilitate within-group economic activities, particularly in contexts with weak formal institutions.
3. **Economic opportunity concentration:** Historical patterns of economic specialization along community lines may influence participation in specific market sectors. Research by Kumar et al. (2021) documents how occupational specialization in Northeast India has frequently developed along community lines due to complex interactions between colonial economic policies, migration patterns, and social stratification.
4. **Regulatory enforcement disparities:** Uneven application of pharmaceutical regulations may create differential incentives across communities. Our key informant interviews suggest potential biases in enforcement attention, though quantifying this phenomenon requires further investigation.

The overrepresentation of Religion A in distribution network leadership and relabeling operations suggests organized structures rather than opportunistic individual vendors. This aligns with research on "parallel governance" systems that emerge when formal regulatory frameworks are perceived as inaccessible or ineffective (Nordstrom, 2010; Bhatia, 2022). The network analysis revealing high within-group density (0.67) compared to between-group connections (0.31) suggests strong community boundary maintenance in distribution operations.

4.2.1 Gender Dimensions of Distribution Networks

The gendered division of labor within distribution networks—with men dominating wholesale (87.3%) and women having significant presence in retail (43.7%)—reflects broader patterns in informal economies. This gender distribution likely intersects with socioeconomic vulnerability, as qualitative data suggests that female vendors are often from economically marginalized households using pharmaceutical sales as a livelihood strategy. The significant variation in female participation across

religious communities (Religion C: 58.2%, Religion A: 37.4%, Religion B: 42.1%) warrants further investigation into how gender norms within communities influence economic role distribution.

4.3 NSAIDs and Chronic Disease Burden

The high prevalence of NSAID-related complications in our study population highlights particular concerns regarding this medication class. Unlike antibiotics, whose misuse primarily creates population-level harm through AMR development, inappropriate NSAID use creates direct individual harm through well-documented pathophysiological mechanisms (McCarberg & Gibofsky, 2022).

The strong association between unauthorized NSAID access and both chronic kidney disease and gastric complications aligns with established literature on NSAID toxicity. However, the prevalence of these complications in our study population exceeds rates typically reported in contexts with regulated pharmaceutical access (Akhund et al., 2021). This disparity likely reflects several factors observed in our study:

1. Absence of appropriate dosing guidance
2. Lack of contraindication screening
3. Extended duration of use without monitoring
4. Potential quality issues affecting medication safety profiles
5. Concomitant use of multiple NSAIDs, increasing toxicity risk

The finding that 62.7% of chronic kidney disease cases were attributable to unauthorized medication use underscores the substantial preventable disease burden created by these practices. This represents a critical opportunity for intervention, as improving pharmaceutical regulation could significantly reduce chronic disease incidence with corresponding reductions in healthcare costs and economic burden.

The high prevalence of gastric complications (78.3% attributable to unauthorized medication) represents a particularly preventable outcome, as proper prescribing would include gastro-protective agents for high-risk patients. The near-complete absence of gastroprotective co-prescription in unauthorized channels (observed in only 3.2% of cases) represents a clear point of clinical difference between regulated and unregulated sources.

4.4 Comparative Context and Theoretical Implications

Our findings contribute to the growing literature on informal pharmaceutical markets by documenting organized distribution structures that challenge simplistic narratives about unregulated medicine sales. Rather than merely representing individual non-compliance with regulations, our research reveals sophisticated parallel systems operating through established community networks.

Unlike similar challenges documented in Cambodia and Laos, where unregulated pharmaceutical distribution has been linked primarily to border porosity

and regulatory capacity limitations (Chuc et al., 2020), the Assam context demonstrates organized community-based networks with strategic regulatory evasion. Similarly, while Latin American studies have emphasized pharmaceutical industry marketing practices in creating demand for inappropriate medication use (Homedes & Ugalde, 2021), our findings highlight consumer-side economic incentives and access limitations as primary drivers.

These findings align with theoretical frameworks on informal governance (Nordstrom, 2010) and institutional voids (Mair et al., 2012), which suggest that parallel systems emerge when formal institutions fail to meet population needs or create prohibitive barriers to access. The religious community patterning of distribution networks demonstrates how social capital can be mobilized to fill these institutional voids, providing economic opportunities for network participants while creating public health risks.

The persistent nature of these networks despite regulatory efforts suggests that effective intervention requires addressing both supply and demand factors simultaneously. This aligns with Ostrom's (2015) institutional analysis framework, which emphasizes that sustainable governance requires alignment between formal rules, community norms, and economic incentives.

4.5 Policy Implications and Regulatory Reform

Our findings highlight the urgent need for comprehensive regulatory reform addressing multiple dimensions of pharmaceutical governance in Assam. Based on our analysis, we propose several priority interventions:

4.5.1 Enhanced Pharmacovigilance

Establishing a robust state-level pharmacovigilance system represents an essential first step. This system should include:

- Active surveillance of medication quality through random sampling
- Adverse event reporting mechanisms accessible to healthcare providers and consumers
- Regular analysis and public reporting of surveillance data
- Cross-verification of pharmaceutical distribution against regulatory databases
- Sentinel surveillance sites in high-risk areas identified through our geospatial analysis

Successful implementation would require an estimated investment of ₹87 crores (US\$11.5 million) over three years, based on costing models from comparable systems in similar contexts. This investment represents just 6.7% of the annual healthcare system costs attributable to unregulated medications.

4.5.2 Coordinated Enforcement

The interstate nature of many distribution networks necessitates coordinated enforcement approaches:

- Joint operations between drug regulatory authorities and commercial tax departments
- Interstate coordination mechanisms targeting cross-border distribution
- Enhanced penalties for organized pharmaceutical fraud
- Specialized prosecution units for pharmaceutical crimes
- Task force implementation at identified high-traffic border points
- Expedited judicial processing for pharmaceutical regulatory violations

Implementation would require regulatory harmonization across neighboring states and establishment of a dedicated pharmaceutical crime unit with estimated annual operational costs of ₹32 crores (US\$4.2 million).

4.5.3 Technology-Enabled Tracking

Implementation of technology solutions could enhance regulatory effectiveness:

- QR code verification systems for legitimate pharmaceuticals
- Blockchain-based supply chain tracking
- Mobile applications enabling consumer verification of medication authenticity
- Digital licensing systems with real-time verification capabilities
- Analytics-driven inspection targeting based on risk assessment
- Automated alerts for suspicious distribution patterns

Successful examples from states like Telangana and Maharashtra provide implementation models, with estimated system development and deployment costs of ₹123 crores (US\$16.2 million) over five years.

4.5.4 Addressing Healthcare Access Barriers

Regulatory enforcement alone is insufficient without addressing underlying healthcare access barriers:

- Expansion of essential medication availability through public health systems
- Community-based chronic disease monitoring programs
- Medication subsidy programs for vulnerable populations
- Mobile healthcare services coordinated with weekly markets
- Streamlined prescription processes for chronic disease medications
- Expanded utilization of pharmacist-led medication management

Implementation would require integration with existing health system strengthening initiatives, with incremental costs estimated at ₹156 crores (US\$20.6 million) annually.

4.5.5 Community Engagement

Effective intervention requires engaging communities currently involved in distribution networks:

- Economic transition programs for vendors

- Community-based regulatory monitoring committees
- Religious leader engagement in promoting appropriate medication use
- Educational interventions targeting high-risk practices
- Alternative livelihood development for network participants
- Collaborative planning processes with community representatives

Implementation would require a phased approach with initial pilot programs in high-prevalence districts, with estimated costs of ₹45 crores (US\$5.9 million) over three years.

4.6 Implementation Pathway

Based on our findings and stakeholder consultations, we propose a three-phase implementation strategy:

Phase 1: Stakeholder Engagement and Infrastructure Development (6 months)

- Establish multi-sector task force with representation from regulatory agencies, healthcare providers, community leaders, and consumer advocates
- Develop detailed implementation plans for each intervention component
- Initiate technology infrastructure development
- Conduct baseline assessments in target areas
- Secure funding commitments for full implementation

Phase 2: Regulatory Infrastructure Enhancement (12 months)

- Deploy technological solutions for pharmaceutical tracking
- Strengthen laboratory capacity for quality testing
- Establish specialized enforcement units
- Develop coordination mechanisms with neighboring states
- Implement training programs for regulatory personnel
- Launch consumer awareness campaigns

Phase 3: Coordinated Enforcement and Monitoring (Ongoing)

- Implement coordinated enforcement operations targeting major distribution networks
- Deploy mobile healthcare services to underserved areas
- Establish community monitoring mechanisms
- Conduct regular impact assessments
- Refine interventions based on emerging data
- Scale successful approaches to additional districts

4.7 Limitations and Future Research

This study has several limitations. First, the sensitive nature of unauthorized pharmaceutical distribution limited our ability to directly observe all aspects of network operations. Second, retrospective assessment of medication use history is subject to recall bias, though we mitigated this through medical record

review and case-control matching. Third, despite anonymization efforts, there remains risk of stigmatization when examining community-specific practices.

Our sampling strategy, while comprehensive for the selected districts, may not capture the full diversity of Assam's pharmaceutical landscape. The economic modeling relies on assumptions about counterfactual scenarios that may not perfectly reflect complex realities. Additionally, the one-year study period may not capture seasonal or long-term trends in distribution patterns.

Future research should examine:

1. Comparative effectiveness of different regulatory interventions through implementation science approaches
2. Longitudinal studies examining health outcomes following regulatory reform
3. Implementation research on technology-enabled pharmaceutical tracking
4. Economic analyses of transition programs for current distribution network participants
5. Cross-regional comparisons to identify generalizable patterns and context-specific factors
6. More detailed analysis of gender dimensions in distribution networks
7. In-depth evaluation of consumer decision-making through behavioral economics approaches
8. Exploration of potential roles for community health workers in safe medication provision

V. Conclusion

This study documents systematic patterns of unregulated pharmaceutical distribution in Assam that demonstrate significant correlation with chronic disease development, economic hardship, and specific religious demographic patterns. The organized nature of distribution networks operating across state boundaries represents a critical challenge for pharmaceutical regulation and public health governance.

The inappropriate dispensing practices and substandard medication quality create ideal conditions for both antimicrobial resistance development and direct medication-induced organ damage, with severe health and economic consequences.

The characterization of these practices as "pharmacy terrorism" is supported by evidence of systematic regulatory evasion resulting in population-level harm. However, addressing these challenges requires nuanced approaches that balance enforcement with healthcare access improvements and community engagement. Implementation of comprehensive pharmacovigilance systems, coordinated cross-sector enforcement, and technology-enabled regulatory

mechanisms represents an urgent priority for protecting public health in Assam.

Our analysis establishes that the economic return on investment for addressing this challenge would be substantial, with potential 5-year returns of ₹23,971 crores (US\$3.16 billion) against required investments of approximately ₹1,823 crores (US\$240.4 million). Beyond economic returns, the potential reduction in preventable suffering through decreased chronic disease burden represents an ethical imperative for action.

The evidence presented here calls for immediate policy attention and resource allocation to address what represents not merely a regulatory challenge, but a fundamental threat to public health security and economic wellbeing in Assam. The pattern of organized distribution along community lines further underscores the need for socially sensitive intervention approaches that address underlying economic and healthcare access factors while enforcing pharmaceutical safety standards.

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ETHICAL CONSIDERATIONS

The study received ethical approval from the Institutional Ethical Committee of Manipur International University, Imphal, Manipur (Approval Number: MIU/IEC/2022/12). All interview participants provided written informed consent, and data were managed in accordance with relevant privacy regulations.

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