



# OVER-THE-COUNTER SALE OF SCHEDULE H AND H1 DRUGS IN GUJARAT: AN ENFORCEMENT-BASED CROSS-SECTIONAL STUDY

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## ABSTRACT:

Schedule H and H1 drugs are prescription-only medications in India, yet unauthorized over-the-counter (OTC) sales remain common, especially in rural and semi-urban regions. Gujarat faces persistent challenges in enforcing these drug regulations. To evaluate the prevalence of unauthorized OTC sales of Schedule H and H1 drugs across 25 districts in Gujarat from April 2024 to April 2025 and assess the effectiveness of enforcement and public awareness efforts. A cross-sectional study using FDCA Gujarat's enforcement data, pharmacist surveys, and pharmacy inspections. Statistical analyses included correlation, regression, and clustering. Of 4,433 firms inspected, 615 (13.88%) were found selling drugs without prescription. High-enforcement districts issued more show-cause notices and suspensions. Strong correlations were observed between inspections and regulatory actions ( $r = 0.71$ ) and between awareness efforts and participant engagement ( $r = 0.99$ ). Pharmacist absenteeism was significantly linked to violations. Widespread non-compliance and weak enforcement persist in several districts. Strengthening inspections, mandating digital H1 records, and expanding AMR awareness programs are essential to improve compliance and reduce public health risks.

**Keywords:** Schedule H, Schedule H1, antimicrobial resistance, pharmacist compliance, FDCA Gujarat, over-the-counter drugs, drug enforcement, public health, India

## 1. Introduction

The unauthorized over-the-counter (OTC) sale of Schedule H and H1 drugs in India poses a growing threat to public health. These drugs, including potent antibiotics, psychotropics, and anti-tubercular agents, are legally restricted for sale only against valid prescriptions issued by registered medical practitioners. However, widespread non-compliance, particularly in rural and semi-urban areas, has resulted in routine OTC dispensing, often without proper documentation or pharmacist oversight. In India, the term "OTC" lacks formal regulatory recognition. While the Drugs and Cosmetics Act, 1940 classifies prescription-only medications under Schedules H, H1, and X, enforcement at the retail level remains inconsistent. Schedule H1, introduced in 2013, mandates record-keeping for 46 critical drugs to control misuse, yet compliance remains weak. Pharmacists frequently face commercial pressure, and unqualified practitioners may recommend or dispense these drugs illegally.

This misuse is directly linked to the rise of antimicrobial resistance (AMR), a national and global public health concern. India has one of the highest rates of antibiotic consumption, and irrational self-medication practices contribute significantly to resistance trends. Despite national action plans and regulatory advisories, local enforcement mechanisms often fail to monitor compliance effectively. Given these challenges, this study aims to evaluate the prevalence of unauthorized OTC sales of Schedule H and H1 drugs in Gujarat, assess the level of pharmacy compliance, and examine community-level practices contributing to AMR. The findings are intended to support policy interventions and strengthen regulatory enforcement at the grassroots level.

## 2. Materials and Methods

### 2.1 Study Design

This study employed a *cross-sectional, mixed-method design*, integrating both *quantitative* and *qualitative* components to evaluate the enforcement of antimicrobial drug regulations and the prevalence of unauthorized sales of Schedule H, H1, and X drugs across 25 districts in Gujarat, India. The study period spanned from April 1, 2024, to April 25, 2025.

## 2.2 Study Objectives

- To evaluate the prevalence of OTC sales of Schedule H/H1/X drugs in urban, semi-urban, and rural regions.
- To assess awareness among consumers and pharmacy workers regarding drug regulations.
- To examine compliance among pharmacies with prescription and record-keeping norms.
- To identify correlations between enforcement activities, pharmacist presence, and unauthorized sales.
- To propose recommendations for regulatory enhancement

## 2.3 Hypotheses

1. A significant relationship exists between the number of firms inspected and the number of Show-Cause Notices (SCNs) issued.
2. Districts with more AMR awareness programs report higher public engagement.
3. Regulatory enforcement is lower in Cluster 2 districts.
4. Absence of a registered pharmacist is significantly associated with unauthorized antimicrobial sales.

## 2.4 Study Setting and Population

The study was conducted across 25 district-level offices of the *Food and Drugs Control Administration (FDCA), Gujarat*. The population included:

- Licensed pharmacies (retail and wholesale)
- FDCA Drug Inspectors and Officers
- Participants of AMR awareness events
- Consumers purchasing antimicrobial drugs

## 2.5 Sampling Technique and Sample Size

A *stratified purposive sampling* strategy was adopted:

- 25 districts were stratified by enforcement intensity.
- 50 pharmacies were selected for direct observational audits.
- 100 individuals, including pharmacy staff and awareness program participants, were surveyed

## 2.6 Data Collection Tools

The study utilized the following instruments:

- (a) *Structured Questionnaire*  
Administered to pharmacy workers and awareness program attendees. It captured:
  - Knowledge of AMR and drug regulations
  - Attitudes toward prescription-only policies
- (b) *Pharmacy Observation Checklist*  
Used to assess:
  - Presence of registered pharmacist
  - OTC sale of antibiotics
  - Schedule H1 register maintenance
  - Display of licences and warnings
- (c) *Secondary Regulatory Data*  
Extracted from FDCA databases:
  - Firms inspected, SCNs issued, licence suspensions/cancellations
  - Drug sample collections
  - Awareness programs and participant counts

## 2.7 Ethical Considerations

- Study adhered to ethical standards per the *Drugs and Cosmetics Act, 1940*.
- *Informed consent* was obtained from all participants.
- *Anonymity and confidentiality* were strictly maintained.

- Participation was voluntary with withdrawal permitted at any stage.

## 2.8 Data Collection Procedure

- Field teams, led by trained FDCA inspectors, conducted:
  - In-person pharmacy audits using *Form 35*
  - Survey distribution at AMR awareness events
  - Compilation of regulatory data from district offices
- Data entry followed a *double-check protocol* for accuracy.

## 2.9 Data Analysis

Statistical analysis was conducted using *SPSS v26* and *Python-based libraries*:

- *Descriptive statistics*: Frequency, percentage, mean
- *Chi-square tests*: Association between location type and violations
- *Correlation (Pearson)*: Relationships between inspections, SCNs, and awareness outcomes
- *Linear regression*: Predictive modeling (e.g., inspections vs. SCNs)
- *PCA + KMeans clustering*: Identified district clusters based on enforcement patterns
- *Visualizations*: Bar plots, scatter plots, and heatmap

## 2.10 Summary of Enforcement Dataset (April 2024–April 2025)

- *Total Firms Inspected*: 4,433
- *Without Prescription Sales Detected*: 615
- *Show-Cause Notices (SCNs) Issued*: 615
- *Licences Suspended*: 603
- *Licences Cancelled*: 11
- *Awareness Programs Conducted*: 19
- *Participants Engaged*: 2,422

## 3. Results

### 3.1 Overview of Inspections and Violations

From April 1, 2024, to April 25, 2025, a total of 4,433 *pharmacy firms* were inspected by FDCA Gujarat across 25 districts. Of these, 615 *firms* (13.88%) were found to be dispensing Schedule H, H1, or X drugs *without valid prescriptions*.

- *Show-Cause Notices (SCNs) Issued*: 615
- *Licences Suspended*: 603
- *Licences Cancelled*: 11
- *Total Registered Firms in Gujarat*: 54,505

The highest incidences of violations were recorded in *Surat* (57 cases), *Valsad* (56 cases), and *Himatnagar* (56 cases).

### 3.2 Enforcement Activity by District

<i>District</i>	<i>Firms Inspected</i>	<i>Without Prescription</i>	<i>SCNs Issued</i>	<i>Licences Suspended</i>	<i>Licences Cancelled</i>
Surat	384	57	57	57	0
Valsad	359	56	56	56	0
Himatnagar	255	56	56	56	5
Vadodara	234	45	45	45	0
Ahmedabad Zone-2	354	45	45	45	1
Others (20 districts)	2,847	356	356	344	5

### 3.3 Awareness Programs and Community Engagement

A total of 19 awareness programs were conducted across the state with 2,422 participants. Districts like Jamnagar, Valsad, and Rajkot showed the highest levels of public engagement, each conducting at least one program with over 250 participants.

District	Awareness Programs	Participants
Valsad	2	500
Rajkot	1	300
Jamnagar	3	250
Vadodara	1	225
Dahod	1	110

### 3.4 Correlation and Regression Analysis

Statistical tests validated key hypotheses:

- *H<sub>1</sub>: Inspections vs. SCNs*
  - Pearson correlation ( $r = 0.71, p < 0.001$ )
  - Regression Equation:  $SCNs = 10.44 + 0.0798 \times \text{Inspections}$
  - $R^2 = 0.506$  — inspections explained ~50.6% of variation in SCNs issued.
- *H<sub>2</sub>: Awareness Programs vs. Participants*
  - Correlation ( $r = 0.99, p < 0.0001$ )
  - Regression Equation:  $Participants = 4.59 + 128.44 \times \text{Programs}$
  - $R^2 = 0.587$
- *H<sub>4</sub>: Pharmacist Absence vs. OTC Sales*
  - Chi-square test  $p < 0.001$
  - Districts with pharmacist absenteeism showed significantly higher OTC violations.

### 3.5 Clustering of Districts (PCA + KMeans Analysis)

Using Principal Component Analysis (PCA) and KMeans clustering on variables such as inspections, SCNs, licence actions, and awareness efforts:

- Cluster 0 (Moderate Enforcement): Includes Godhra, Nadiad, Mehsana
- Cluster 1 (High Enforcement): Surat, Vadodara, Ahmedabad zones
- Cluster 2 (Low Enforcement): Patan, Porbandar, Tapi

### 3.6 Summary of Key Findings

- 13.88% of inspected firms were selling prescription drugs OTC.
- Enforcement actions (SCNs, suspensions) were strongly correlated with inspection intensity.
- Awareness efforts significantly increased community participation.
- Districts with low inspection rates and pharmacist absenteeism had higher OTC sales.
- Digital record-keeping and pharmacist verification were generally lacking across low-performing districts.

## 4. Discussion

The findings of this study highlight systemic challenges and gaps in the enforcement of prescription drug regulations across Gujarat. Despite robust legal frameworks under the Drugs and Cosmetics Act, 1940, a significant number of retail pharmacies continue to dispense Schedule H and H1 drugs without valid prescriptions. Out of 4,433 firms inspected across 25 districts, 615 (13.88%) were found violating the law, indicating persistent non-compliance in the pharmaceutical retail sector.

### 4.1 Regional Disparities and Enforcement Gaps

The data revealed notable disparities in regulatory performance across districts. High-performing zones such as Surat, Vadodara, and Ahmedabad demonstrated proactive inspection regimes, resulting in higher numbers of show-cause notices and licence suspensions. In contrast, districts like Patan, Porbandar, and Tapi exhibited low inspection and awareness activity, indicating weaker regulatory presence. These low-enforcement zones were also characterized by limited awareness campaigns and poor pharmacist accountability.

#### 4.2 Correlation Between Inspection and Compliance

A statistically significant correlation was observed between the number of inspections and enforcement actions taken ( $r = 0.71$ ,  $p < 0.001$ ). Districts with more frequent inspections reported a proportionate increase in SCNs and licence suspensions, supporting the hypothesis that regulatory vigilance is critical to ensuring compliance.

#### 4.3 Community Awareness and AMR Risk

Awareness programs had a strong impact on public engagement ( $r = 0.99$ ,  $p < 0.0001$ ), reinforcing the role of health education in curbing OTC misuse. Despite this, only 19 awareness events were conducted across the state, revealing a missed opportunity to influence consumer behavior at scale. The link between unauthorized antimicrobial sale and rising AMR remains a significant public health threat. Absence of pharmacists at retail counters was strongly associated with illegal OTC dispensing, reaffirming the need for continuous presence and professional accountability.

#### 4.4 Policy Implications

The continued prevalence of OTC sales, especially of antibiotics, underscores the urgency of integrating enforcement with public health strategies. Digital tracking of Schedule H1 sales, real-time pharmacist verification, and standardized penalties for non-compliance are essential reforms.

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### 5. Recommendations

Based on the findings, the following recommendations are proposed

#### 5.1 Strengthen Regulatory Surveillance

- Implement *randomized inspections* in low-enforcement districts like Patan and Porbandar.
- Increase *field force allocation* and training for FDCA inspectors in underserved zones

#### 5.2 Digital Compliance Infrastructure

- Develop a *state-wide digital prescription audit system* to track sales of Schedule H and H1 drugs.
- Mandate *electronic Schedule H1 registers* for real-time pharmacist documentation.

#### 5.3 Pharmacist Accountability

- Introduce *QR code-based verification* of pharmacist registration at retail counters.
- Suspend or cancel licences for firms repeatedly operating without qualified personnel.

#### 5.4 Expand Awareness and AMR Campaigns

- Scale up *AMR sensitization programs* in rural areas through partnerships with NGOs and public health workers.
- Use *vernacular media and visual materials* at PHCs and pharmacies to educate consumers on the risks of self-medication.

#### 5.5 Policy and Penal Reforms

- Create *uniform enforcement protocols* for licence suspension and cancellation.
- Integrate *cluster-based monitoring* using PCA-KMeans analysis to flag high-risk districts for priority intervention.

#### 5.6 Encourage E-Prescription Adoption

- Promote use of *e-prescription systems* in PHCs and private clinics with built-in alerts for Schedule H/H1 drugs.
- Link e-prescriptions with retail pharmacy sales to detect irregularities.

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