

Chapter 15

Selling Without Prescription – A Grey Market of Medicines

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Introduction: Medicine Over the Counter – Without the Rules

India's pharmacies operate in a paradox: while thousands of medicines are legally categorized as prescription-only, **it is widely possible to purchase them over the counter without any medical consultation.** This unregulated access creates a thriving grey market—one where Schedule H, H1, and even Schedule X drugs are casually dispensed, turning retail counters into **pseudo-diagnostic booths.**

This chapter explores the **depth and dangers of non-prescription drug sales**, unpacking the public health risks, regulatory failures, and moral hazard it fosters within India's retail pharma landscape.

1. Schedule H and Beyond: What the Law Says

Under the **Drugs and Cosmetics Rules, 1945**, several drug categories are restricted:

- **Schedule H:** Prescription-only drugs (e.g., antibiotics, antihypertensives)
- **Schedule H1:** Additional surveillance; pharmacists must maintain a register (e.g., fluoroquinolones, opioids)
- **Schedule X:** Narcotics and psychotropics (e.g., morphine, barbiturates)

Legal

Requirement:

To be sold only on the presentation of a **valid, signed prescription**
Pharmacist must maintain **sale records** for H1/X drugs

Yet, field studies show that **more than 60% of Schedule H drugs are dispensed without prescriptions** [1].

2. Drivers of the Grey Market

a) Patient Demand

- Convenience: “Why go to a doctor for a fever?”
- Cost-saving: Consultation is more expensive than the pill
- Reuse of old prescriptions or expired slips

b) Chemist Incentives

- Increased sales
- Pushing high-margin brands
- No penalty for violation (low enforcement)

c) Systemic Failure

- Absence of electronic prescription verification
- Weak inspection frameworks
- Collusion in some districts between inspectors and pharmacies

3. Real-World Snapshot: What Happens at the Counter

“You describe your problem, the chemist hands you medicine. Sometimes even injects it.” – Rural patient, Haryana

Common Drugs Sold Without Prescription (2022 Study):

| Table 1: Drug Type vs % Non-Prescription Sales (Urban India) |

Drug Category	% Sold OTC Without Prescription
Antibiotics (azithromycin)	74%
Steroids (prednisolone)	58%
Benzodiazepines (alprazolam)	41%
Antifungals (fluconazole)	64%
Antidiabetics (metformin)	35%

Source: AIIMS-Pharmacovigilance Study, 2022 [2]

4. The Public Health Consequences

a) Antimicrobial Resistance (AMR)

OTC sales of antibiotics for viral fevers, coughs, and minor aches have **accelerated India’s AMR burden**, now among the **highest globally**.

“One in three cases of pneumonia in Indian ICUs is now resistant to first-line drugs.” – ICMR AMR Report, 2022 [3]

b) Steroid Abuse

Long-term misuse of corticosteroids (for pain, skin whitening, asthma) has led to:

- Immunosuppression
- Bone loss
- Adrenal failure

c) Benzodiazepine Dependence

Sedatives like **alprazolam and clonazepam** are sold freely. Prolonged use without supervision leads to:

- Tolerance and addiction
- Withdrawal seizures
- Depression and memory impairment

5. The Economics of Rule Violation

| **Table 2: Incentive Analysis for Chemist to Sell Without Prescription** |

Parameter	Estimate
Cost of fine (if caught)	₹3,000–₹5,000
Extra monthly profit (per drug class)	₹15,000–₹40,000
Risk of license cancellation	Very Low
Likelihood of inspection	Once in 2–5 years

The **low risk–high reward** structure makes unethical OTC sales a calculated choice, not an accident.

6. Schedule H1 Registers: A Dead Letter

Introduced in 2014, Schedule H1 mandates:

- Maintaining a register of sales
- Name, address of patient
- Prescribing doctor's contact

Ground Reality:

- Registers are often blank or falsified
- Recycled prescriptions are reused
- Pharmacists claim patients “don't cooperate”

In a 2023 audit of 300 chemists in Maharashtra, only **14% maintained correct H1 registers** [4].

7. Policy Gaps and Weak Enforcement

a) Digital Prescription Authentication

No e-prescription tracking system exists that links doctor issuance to chemist verification.

b) No Mandatory CCTV or Barcode Scans

Unlike some countries, pharmacies are not required to record sales via **track-and-trace barcoding**.

c) Undertrained Drug Inspectors

Most are burdened with **inspections, prosecutions, and admin work**, with **no performance metrics** tied to illegal OTC sales.

d) Legal Grey Zones

Many states allow “provisional” drug licenses, sometimes for **up to 1 year without scrutiny**.

8. Public Attitudes: Medicine as Convenience, Not Caution

Indians often trust their chemist more than doctors—especially for recurring ailments.

“We take the same cough syrup and painkiller every time. Why waste money on another visit?” – Patient, Jaipur

This mindset perpetuates the grey market, reinforced by:

- Past success with self-medication
- High out-of-pocket healthcare costs
- Cultural acceptance of “quick fixes”

9. Technology and Reform Opportunities

| **Table 3: Technological Interventions for Safer Dispensing** |

Technology	Status in India
ePrescription + QR validation	Pilot (Kerala)
Aadhaar-linked patient profiles	Proposed (2021)
Real-time drug sale reporting	Used in private chains
Prescription tracking dashboard	Not implemented

A centralised eRx system (like Estonia’s or Sweden’s) could **link doctor prescription to chemist sale**, closing the loop.

10. A Path Forward: Policy and Cultural Change

| **Table 4: Recommended Actions to Curb Non-Prescription Sales** |

Action	Feasibility
Enforce CCTV + electronic registers	High
Penalise repeated OTC violations	Medium
Reward ethical compliance	High
Mass awareness on self-medication risks	Medium
Ban license “renting” and proxies	High

Incentivising ethical retail behaviour, rather than just punishing unethical ones, may offer a **sustainable route forward**.

Conclusion: The Cost of Convenience

In India’s pharmacy landscape, the **ease of buying medicine without prescriptions** comes at a steep cost: resistance, addiction, toxicity, and lost trust.

The longer this grey market flourishes unchecked, the more fragile our drug safety system becomes. Real reform must go beyond lawbooks—it requires cultural shift, technological integration, and ethical business practices.

Until then, a simple visit to a chemist may continue to be more dangerous than it seems.

References

1. Ministry of Health and Family Welfare. OTC Drug Sales and Regulatory Non-Compliance Survey. MoHFW; 2022.
2. AIIMS-Pharmacovigilance Division. Drug Dispensing Practices in Urban India. New Delhi; 2022.
3. Indian Council of Medical Research. Antimicrobial Resistance Surveillance Report. ICMR; 2022.
4. Maharashtra State FDA. Schedule H1 Compliance Audit. Mumbai; 2023.
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