

## **The Role of Pharmacists in Antimicrobial Stewardship in India: Challenges, Opportunities, and Future Directions**

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### **Abstract**

Antimicrobial resistance (AMR) has emerged as a critical public health challenge in India, driven by a high burden of infectious diseases, widespread antibiotic misuse, and variable regulatory enforcement. India is one of the world's largest consumers of antibiotics, with inappropriate prescribing and non-prescription dispensing contributing significantly to resistance. Pharmacists, positioned at the interface between prescribers and patients, play a pivotal role in antimicrobial stewardship (AMS) across hospital and community settings. This review examines the role of pharmacists in curbing AMR in the Indian context, focusing on regulatory frameworks such as Schedule H and H1, hospital-based antimicrobial stewardship programs, and the evolving responsibilities of community pharmacists. Evidence from Indian and global studies demonstrates that pharmacist-led interventions improve rational antibiotic use, reduce inappropriate prescribing, and lower healthcare costs. However, challenges including workforce shortages, limited infectious disease training, commercial pressures, and weak enforcement persist. Strengthening pharmacist-led stewardship through policy support, education, and integration into national AMR strategies is essential for preserving antibiotic efficacy in India.

**Keywords:** Antimicrobial resistance, antimicrobial stewardship, pharmacists, India, Schedule H1, community pharmacy

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### **Introduction**

Antimicrobial resistance threatens the foundations of modern medicine by reducing the effectiveness of antibiotics used to treat common infections. Globally, AMR is responsible for millions of deaths annually, and projections indicate a continued rise if current trends persist [1,2]. India bears a disproportionate burden of this crisis due to its high infectious disease prevalence, large population, and extensive antibiotic consumption [3].

India is among the world's largest consumers of antibiotics, with community-level misuse being a major driver of resistance [4]. Inappropriate prescribing, incomplete treatment courses, self-medication, and over-the-counter (OTC) sale of antibiotics have

been consistently reported across urban and rural settings [5]. The World Health Organization and India's National Centre for Disease Control (NCDC) recognize antimicrobial stewardship as a cornerstone strategy for addressing AMR [6].

Pharmacists, both in hospitals and community pharmacies, are uniquely positioned to influence antimicrobial use. As medication experts and accessible healthcare professionals, pharmacists can ensure rational antibiotic selection, dosing, duration, and patient adherence. This review critically examines the role of pharmacists in antimicrobial stewardship within the Indian healthcare system, highlighting regulatory mechanisms, evidence of impact, and future directions.

### **Antimicrobial Resistance in the Indian Context**

India faces a complex AMR landscape characterized by high resistance rates among common pathogens such as *Escherichia coli*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, and *Staphylococcus aureus* [6]. Resistance to last-resort antibiotics, including carbapenems and colistin, has been increasingly reported from tertiary care hospitals [7].

Several factors contribute to this situation:

- High burden of communicable diseases
- Easy access to antibiotics without prescription
- Inadequate diagnostic facilities at primary care level
- Limited awareness among patients regarding appropriate antibiotic use
- Variable enforcement of drug regulations

The COVID-19 pandemic further exacerbated antibiotic misuse due to empiric prescribing for viral infections and fear-driven self-medication [8].

### **Regulatory Framework Governing Antibiotic Use in India**

#### **Schedule H and Schedule H1**

In India, antibiotics are regulated under the Drugs and Cosmetics Rules, 1945, primarily through **Schedule H** and the stricter **Schedule H1**. Implemented in 2014, Schedule H1 requires prescription-only dispensing, maintenance of sales records for three years, and red-box labeling to warn against misuse. Enforcement, however, remains inconsistent, particularly in small retail pharmacies, underscoring the crucial role of pharmacists in ensuring compliance [9].

#### **National Action Plan on Antimicrobial Resistance (NAP-AMR)**

India's NAP-AMR (2017–2021; extended) emphasizes optimizing antimicrobial use through stewardship, surveillance, and education [6]. Pharmacists are explicitly recognized as key stakeholders in implementing rational drug use and public awareness initiatives.

#### **FIP Commission on Antimicrobial Resistance**

The International Pharmaceutical Federation (FIP) supports global efforts to combat antimicrobial resistance (AMR) by engaging pharmacists in surveillance, regulation, and rational use of antibiotics. To strengthen these initiatives, FIP established the Commission on AMR, a network of experts that facilitates knowledge exchange, provides guidance, and enables targeted action aligned with the World Health Organization's AMR priorities. Through this Commission, FIP underscores the pivotal

role of pharmacists in antimicrobial stewardship and coordinated global AMR containment.

### **Role of Pharmacists in Hospital-Based Antimicrobial Stewardship**

#### **Participation in Antimicrobial Stewardship Programs**

In tertiary and secondary care hospitals, pharmacists serve as core members of antimicrobial stewardship programs (ASPs), often alongside infectious disease physicians and microbiologists. Indian studies have shown that pharmacist involvement improves guideline adherence and reduces inappropriate antibiotic use [10].

#### **Prospective Audit and Feedback**

Clinical pharmacists review antibiotic prescriptions and provide feedback on de-escalation, dose adjustment, and duration based on microbiological data. This approach has been shown to reduce broad-spectrum antibiotic use without negatively affecting patient outcomes [11].

#### **Dose Optimization and Therapeutic Drug Monitoring**

Pharmacists apply pharmacokinetic and pharmacodynamic principles to optimize dosing, particularly for drugs such as vancomycin, aminoglycosides, and colistin. Dose optimization reduces toxicity and minimizes selective pressure for resistance [12].

#### **Formulary Restriction and Guideline Development**

Hospital pharmacists contribute to antimicrobial formulary management, restricting high-end antibiotics and developing institution-specific treatment guidelines aligned with national and international recommendations [13].

### **Role of Community and Retail Pharmacists in India**

#### **Rational Dispensing and Gatekeeping**

Community and retail pharmacists in India play a pivotal role in promoting rational antibiotic use. Acting as primary points of contact, they serve as gatekeepers by verifying prescriptions and refusing inappropriate antibiotic requests, thereby reducing misuse [5]. Additionally, pharmacists provide patient education on completing full antibiotic courses, avoiding self-medication, and understanding that antibiotics are ineffective against viral infections. Evidence from Indian community pharmacies indicates that such educational interventions enhance adherence and decrease demand for unnecessary antibiotics [14].

#### **Vaccination and Infection Prevention**

Although still emerging in India, pharmacist-led vaccination initiatives can reduce the incidence of preventable infections, thereby lowering antibiotic demand. Promotion of influenza and pneumococcal vaccination is particularly relevant for high-risk populations [15].

### **Evidence of Impact from Indian Studies**

Several Indian studies highlight the effectiveness of pharmacist-led antimicrobial stewardship:

- Quasi-experimental studies from tertiary hospitals have demonstrated reductions in antibiotic consumption and improved appropriateness following pharmacist-led interventions [10,11].
- Community-based surveys show that trained pharmacists are significantly less likely to dispense antibiotics without prescriptions [5].
- Economic analyses indicate cost savings through reduced antibiotic use and shorter hospital stays [13].

These findings align with global evidence supporting pharmacist involvement in AMS.

### **Challenges Specific to India**

Despite the demonstrated benefits of pharmacist-led antimicrobial stewardship in India, several barriers impede its effective implementation. Limited formal training in infectious diseases and antimicrobial stewardship, coupled with shortages of clinical pharmacists in public hospitals, constrain professional capacity. Additionally, commercial pressures in retail pharmacies, inconsistent enforcement of Schedule H1 regulations, and persistent patient demand for antibiotics further undermine rational use. Overcoming these challenges necessitates comprehensive systemic and policy-level interventions to strengthen the role of pharmacists in antimicrobial stewardship.

### **Future Directions and Recommendations**

To strengthen pharmacist-led antimicrobial stewardship in India, a multifaceted approach is essential. Education and training form the foundation: antimicrobial stewardship (AMS) principles should be systematically integrated into undergraduate and postgraduate pharmacy curricula to ensure that pharmacists enter practice with a solid understanding of rational antibiotic use. Beyond formal education, continuing professional development programs, including mandatory AMS training for licensed pharmacists, can maintain and update clinical competencies throughout their careers.

Policy integration is another critical step. Pharmacists should be formally recognized as key stakeholders in national and state-level AMR programs, enabling them to contribute actively to surveillance, guideline implementation, and stewardship initiatives. To encourage clinical engagement, remuneration models in both hospital and community settings should transition from a product-based framework to service-oriented incentives that reward patient-centered care and adherence to stewardship practices.

Finally, public engagement and awareness are vital. Pharmacy-led educational campaigns, aligned with national AMR initiatives, can inform communities about the dangers of antibiotic misuse, the importance of completing prescribed courses, and the ineffectiveness of antibiotics against viral infections. Coordinated efforts across education, policy, clinical practice, and public outreach will enhance the capacity of pharmacists to act as frontline defenders against antimicrobial resistance in India.

### **Conclusion**

Pharmacists represent a critical yet underrecognized resource in India's ongoing battle against antimicrobial resistance (AMR). Their strategic positioning within both hospital and community settings allows them to act as frontline defenders against the misuse and overuse of antibiotics. Through targeted stewardship activities in healthcare

facilities and rational dispensing practices in community pharmacies, pharmacists can substantially reduce inappropriate antibiotic utilization, promote adherence to treatment guidelines, and provide essential patient education.

However, to fully realize this potential, systemic enhancements are required. Strengthening regulatory enforcement, particularly of Schedule H and H1 provisions, is essential to curb unauthorized antibiotic sales. Simultaneously, incorporating antimicrobial stewardship into pharmacy education, providing continuous professional development opportunities, and creating supportive policy frameworks will empower pharmacists to act decisively as stewards of antibiotic use.

Integrating pharmacist-led stewardship into India's broader national and state-level AMR strategies is vital for ensuring the rational use of antimicrobials, mitigating the spread of resistance, and preserving the long-term efficacy of antibiotics. Such comprehensive, coordinated efforts will not only enhance patient outcomes but also safeguard public health for future generations.

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