



Research Article

IMPACT OF REGULATORY COMPLIANCE ON THE OPERATIONAL EFFICIENCY OF COMMUNITY PHARMACIES IN INDIA: A PHARMACY MANAGEMENT AND LEGAL PERSPECTIVE

Author: Satyadev Varundiya^{1*}, Pankaj Surywanshi

^{1,2} Faculty of Pharmacy, Acharya Rajendra Suri Shiksha Mahavidhyalaya (ARSSM) College of Pharmacy, Mandsaur (M.P.), 458002

KEYWORDS:

Community pharmacy;
regulatory compliance;
pharmacy management;
operational efficiency;
Pharmacy Act; Drugs and
Cosmetics Rules

ARTICLE HISTORY

Received Date: 07/07/2026

Revised Date: 10/07/2026

Accepted Date: 07/08/2026

Published Date: 01/09/2026

DOI: 10.69557/2czdkk06

CORRESPONDING AUTHOR

Satyadev Varundiya

satyade1315@gmail.com

ABSTRACT

Community pharmacies represent an important point of access to medicines and pharmaceutical services in India, where regulatory requirements are closely related to prescription handling, documentation, inventory management, dispensing practices and professional responsibilities. The present study examined the association between regulatory compliance and operational efficiency in community pharmacies from pharmacy-management and legal perspectives. A cross-sectional observational assessment was conducted among 120 community pharmacies using a structured regulatory-compliance checklist and an operational-efficiency assessment tool. Regulatory compliance was assessed across six domains: legal and pharmacist-related compliance, prescription and dispensing compliance, Schedule H/H1/X compliance, storage and inventory management, documentation, and professional services. Operational performance was assessed using prescription-processing time, inventory-record accuracy, documentation completeness, workflow standardization and service-related indicators. Each regulatory-compliance item was scored as compliant or non-compliant, producing a maximum compliance score of 30, while operational-efficiency practices were assessed using a 20-item tool with a maximum score of 20. The mean overall regulatory-compliance score was $23.40 \pm 3.70/30$ (78.0%), while the mean operational-efficiency score was $15.90 \pm 2.40/20$ (79.5%). Prescription verification was demonstrated in 105 (87.5%) pharmacies, while complete prescription-related documentation was demonstrated in 86 (71.7%) pharmacies. The mean prescription-processing time was 4.8 ± 1.3 min and mean inventory-record accuracy was $91.8 \pm 6.4\%$. Pearson correlation analysis demonstrated a positive association between overall regulatory compliance and operational efficiency ($r = 0.68$, $p < 0.001$). Positive associations were also observed with inventory-record accuracy ($r = 0.55$), documentation completeness ($r = 0.63$), prescription-processing efficiency ($r = 0.49$), and workflow standardization ($r = 0.61$). The findings indicate that stronger regulatory compliance tended to coexist with better operational organization. Because the study used a cross-sectional observational design, the findings demonstrate association rather than causation. Strengthening standardized procedures, pharmacist training, internal audits, documentation systems, inventory reconciliation and appropriate digital record management may support regulatory adherence and operational organization.

INTRODUCTION

Community pharmacies represent an important interface between the healthcare system and the public because patients frequently obtain medicines and medicine-related information through retail pharmacies. In India, community pharmacy practice has traditionally emphasized medicine supply, while professional expectations increasingly include patient counselling, medication-related services and responsible medicine management ^[1]. The legal framework governing pharmacy practice includes the Pharmacy Act, 1948, which regulates the profession and registration of pharmacists ^[2]. The Drugs and Cosmetics Act, 1940, provides the legal framework for the import, manufacture, distribution and sale of drugs and cosmetics ^[3].

The Pharmacy Practice Regulations, 2015 further describe professional responsibilities associated with prescription interpretation, dispensing, patient counselling and pharmaceutical care ^[4]. Good Pharmacy Practice emphasizes appropriate procurement, storage, security, distribution, dispensing, medication management and continuing professional development ^[5]. Therefore, regulatory compliance in community pharmacy extends beyond possession of a valid licence and encompasses several routine operational and professional activities.

Prescription-controlled medicines represent an important component of regulatory compliance. Schedule H and Schedule X medicines are subject to prescription requirements, whereas Schedule H1 medicines are subject to additional recording and monitoring requirements ^[6]. Regulatory requirements relating to prescription verification and traceable documentation are particularly important for maintaining accountability in retail pharmacy practice ^[7]. Previous Indian studies have reported challenges involving inappropriate nonprescription antibiotic dispensing, limited regulatory awareness, commercial pressures and inadequate understanding of antimicrobial-resistance-related responsibilities among some pharmacy personnel ^[8–10].

Professional pharmacy services may also be affected by operational constraints. Community pharmacists have reported barriers to patient counselling, including inadequate knowledge, limited confidence, time constraints and insufficient opportunities for professional development ^[11]. These issues demonstrate that regulatory compliance and pharmacy management are closely connected components of community pharmacy practice.

From a management perspective, standardized compliance procedures may support consistency in documentation, inventory management, prescription handling and accountability ^[12]. Compliance requirements may therefore be relevant not only to legal inspection but also to the organization of day-to-day pharmacy activities. However, the relationship between regulatory compliance and operational performance should be evaluated using clearly differentiated measures to avoid measuring the same construct twice.

Accordingly, the present study examined the association between regulatory compliance and operational efficiency in community pharmacies in India. The study focused on legal and pharmacist-related requirements, prescription and dispensing practices, Schedule H/H1/X medicine handling, storage and inventory management, documentation and professional services, together with selected indicators of operational performance.

Operational Definitions

Regulatory compliance

Regulatory compliance was defined as the extent to which a community pharmacy demonstrated adherence to applicable legal, professional, documentation, dispensing, storage and medicine-handling requirements assessed through the structured compliance checklist.

Operational efficiency

Operational efficiency was defined as the degree to which routine pharmacy activities were organized, standardized and completed with appropriate use of time and resources, as assessed through operational indicators such as prescription-processing time, workflow standardization, record retrieval, staff allocation and service delays.

Organized/chain pharmacy

An organized/chain pharmacy was defined as a pharmacy outlet operating under a common organizational structure, standardized management system or multiple-outlet business model. An independent pharmacy was defined as a separately operated retail pharmacy without such a chain structure.

Workflow deviation

Workflow deviation referred to an interruption, departure or inconsistency from the pharmacy's usual standardized sequence of activities during prescription processing, dispensing, documentation, inventory handling or related services.

Documentation completeness

Documentation completeness referred to the extent to which required pharmacy records were available, complete, appropriately maintained and readily retrievable during assessment.

RESEARCH METHODOLOGY

Study Design and Setting

A cross-sectional observational study was conducted to examine regulatory compliance and operational efficiency among community pharmacies in India. The assessment was conducted over a period of six months.

Community pharmacies operating as retail medicine outlets and dispensing medicines directly to patients were eligible for assessment. Pharmacies functioning exclusively as wholesale establishments or not dispensing medicines directly to patients were excluded.

The assessment focused on actual implementation of regulatory and professional requirements rather than merely confirming possession of a drug license. Legal, professional, documentation, storage, dispensing, inventory and workflow-related parameters were assessed.

Study Population and Sampling

A total of 120 community pharmacies were assessed. Convenience sampling was used to recruit participating pharmacies, with an attempt to include both independent and organized/chain pharmacy outlets from urban and semi-urban settings.

At each participating pharmacy, the pharmacist or responsible pharmacy personnel were approached, and the purpose and procedure of the assessment were explained. Participation was voluntary. Information was recorded without identifying individual pharmacies in the analytical dataset.

Sample-Size Consideration

The final analytical sample comprised 120 community pharmacies. The sample size was determined

according to the accessible population and feasibility of conducting structured pharmacy-level observations during the study period.

Because the supplied study record does not document a formal a priori power calculation, the present sample should be interpreted primarily in the context of the observed associations rather than as evidence of population-wide estimates.

Development of the Regulatory-Compliance Checklist

A structured regulatory-compliance checklist was developed from the Pharmacy Act, 1948, Drugs and Cosmetics Act, 1940, Drugs and Cosmetics Rules, 1945, Pharmacy Practice Regulations, 2015, and principles of Good Pharmacy Practice [2–5].

The checklist comprised **30 items distributed across six domains**:

1. Legal and pharmacist-related compliance
2. Prescription and dispensing compliance
3. Schedule H/H1/X compliance
4. Storage and inventory compliance
5. Documentation and record maintenance
6. Professional services

Each item was scored as 1 for compliance and 0 for non-compliance. The maximum possible compliance score was therefore 30.

The percentage compliance score was calculated as:

$$\text{Compliance (\%)} = (\text{Number of compliant items} / 30) \times 100$$

Pharmacies were classified according to the following predefined categories:

- High compliance: $\geq 80\%$
- Moderate compliance: 60–79%
- Low compliance: $< 60\%$

Table 1. Regulatory-Compliance Assessment Domains

Domain	No. of items	Major parameters assessed
Legal/pharmacist compliance	5	Pharmacist registration, pharmacist availability, licence display and statutory requirements
Prescription/dispensing	6	Prescription verification, patient details, dose/strength checking and labelling
Schedule H/H1/X compliance	5	Prescription requirements, separate records and restricted-sale practices
Storage/inventory	5	Temperature, expiry monitoring, stock rotation and segregation
Documentation	5	Purchase/sales records, prescription records and registers
Professional services	4	Counselling, confidentiality, medicine information and professional conduct
Total	30	—

Assessment of Operational Efficiency

Operational efficiency was assessed using a structured 20-item tool. To minimize conceptual overlap with the regulatory-compliance construct, operational efficiency was considered primarily in terms of **workflow performance and resource organization**, including:

- prescription-processing workflow;
- prescription-processing time;
- stock availability and organization;
- workflow interruption;
- staff allocation;
- record retrieval;
- service delays;
- workflow standardization;
- dispensing sequence;
- labelling workflow;
- operational coordination.

Each satisfactory operational practice received one point, producing a maximum operational-efficiency score of 20.

The operational-efficiency percentage was calculated as:

$$\text{Operational efficiency (\%)} = (\text{Obtained score} / 20) \times 100$$

Prescription-Processing Time

Prescription-processing time was recorded from the point at which a prescription was presented to the pharmacist until the medicines were prepared and ready for handover. Prolonged patient consultation unrelated to dispensing was excluded from the timing measurement.

Three routine prescriptions were observed at each pharmacy, and the mean processing time was calculated for each pharmacy.

Inventory-Record Accuracy

Inventory accuracy was assessed by comparing selected physical stock quantities with the corresponding recorded quantities. Ten commonly dispensed medicines were selected from each pharmacy.

Inventory accuracy was calculated as:

$$\text{Inventory accuracy (\%)} = (\text{Number of correctly matched stock records} / 10) \times 100$$

Expiry-management practices were assessed separately by determining whether near-expiry medicines were identifiable, appropriately segregated and managed according to the pharmacy's documented procedure.

Documentation Assessment

Documentation was assessed by reviewing available purchase records, prescription records, restricted-medicine registers, invoices and other applicable statutory documentation.

Particular attention was given to Schedule H1-related records because the applicable regulatory framework requires specified information to be recorded and retained for inspection [6].

Patient-Counselling Assessment

Patient counselling was assessed using four observable parameters:

1. Indication/use
2. Dose and administration
3. Precautions/adverse effects
4. Adherence-related advice

A counselling score was determined according to the number of relevant parameters appropriately communicated during observed dispensing interactions.

Data-Collection Procedure

The investigator visited participating pharmacies and completed the assessment through direct observation, document verification and structured interaction with pharmacy personnel.

Operational observations were conducted during routine pharmacy activities without intentionally altering the normal workflow.

The assessment form was pilot-tested in **10 pharmacies** that were not included in the final sample. Ambiguous checklist items were revised following the pilot assessment before the main data collection.

Observer Training and Quality Control

Before formal data collection, the investigator reviewed the assessment criteria and scoring rules to ensure consistent interpretation of checklist items.

For each assessment, the same operational definitions and scoring criteria were applied. Direct observation and document verification were used wherever applicable rather than relying exclusively on verbal responses.

Where multiple observers were involved, inter-rater agreement should be reported in the final manuscript. The supplied study record does not contain a numerical inter-rater reliability estimate.

Ethical Considerations

Participation by pharmacy personnel was voluntary. The assessment was conducted with attention to confidentiality, and individual pharmacy identities were not included in the analytical dataset. No personal patient information was copied or entered into the study database.

Statistical Analysis

Data were summarized using mean $\pm$ standard deviation, frequency and percentage.

Pearson's correlation coefficient (**r**) was used to examine the association between regulatory-compliance scores and operational-efficiency scores. Correlations with selected operational indicators were also examined.

A two-tailed p value <0.05 was considered statistically significant.

Because the study was cross-sectional, correlation coefficients were interpreted as measures of association rather than evidence of causality.

For future or extended analysis, multivariable regression may be used to account for potentially relevant organizational characteristics, including:

- pharmacy type;
- urban/semi-urban location;
- years of operation;
- staffing level;
- workload or prescription volume; and

- use of digital pharmacy-management systems.

RESULTS

General Characteristics of Assessed Pharmacies

A total of **120 community pharmacies** were included in the analysis. Of these, 74 (61.7%) were independent pharmacies and 46 (38.3%) were organized/chain pharmacies. Seventy-eight pharmacies (65.0%) were located in urban areas and 42 (35.0%) in semi-urban areas.

A registered pharmacist was routinely available during operating hours in 103 (85.8%) pharmacies, whereas continuous pharmacist availability could not be demonstrated in 17 (14.2%) pharmacies. Eighty-two pharmacies (68.3%) had been operational for more than five years, while 38 (31.7%) had been operational for five years or less.

Table 2. General Characteristics of Community Pharmacies

Characteristic	Number	Percentage
Total pharmacies assessed	120	100.0
Independent pharmacies	74	61.7
Organized/chain pharmacies	46	38.3
Urban pharmacies	78	65.0
Semi-urban pharmacies	42	35.0
Pharmacist routinely available	103	85.8
Continuous pharmacist availability not demonstrated	17	14.2
Pharmacy operational >5 years	82	68.3
Pharmacy operational ≤5 years	38	31.7

Regulatory-Compliance Performance

The mean overall regulatory-compliance score was **23.40 ± 3.70 out of 30**, corresponding to **78.0% compliance**.

The highest domain score was observed for legal/pharmacist-related compliance (88.4%), followed by prescription/dispensing compliance (80.3%). Professional services showed the lowest domain score (68.0%), followed by documentation (72.2%).

Prescription verification was demonstrated in 105 (87.5%) pharmacies. However, systematic documentation of prescription details, including dose, strength, duration and patient-related information, was not consistently demonstrated across all pharmacies.

Table 3. Regulatory-Compliance Performance by Domain

Compliance domain	Maximum score	Mean score ± SD	Compliance (%)
Legal/pharmacist compliance	5	4.42 ± 0.73	88.4
Prescription/dispensing	6	4.82 ± 0.91	80.3
Schedule H/H1/X compliance	5	3.89 ± 1.04	77.8
Storage/inventory	5	3.94 ± 0.88	78.8
Documentation	5	3.61 ± 1.02	72.2
Professional services	4	2.72 ± 0.89	68.0
Overall	30	23.40 ± 3.70	78.0

Prescription and Restricted-Medicine Practices

Prescription verification was demonstrated in **105 pharmacies (87.5%)**. Schedule H/H1/X prescription-handling requirements were satisfactorily demonstrated by **94 pharmacies (78.3%)**.

A separate and systematically maintained record for applicable Schedule H1 medicines was demonstrated by **89 pharmacies (74.2%)**.

These findings indicate that prescription verification was relatively well established, whereas systematic restricted-medicine documentation was less consistently demonstrated.

Storage and Inventory Management

Appropriate storage arrangements were observed in **101 pharmacies (84.2%)**. Expiry-date monitoring was documented in **96 pharmacies (80.0%)**, while systematic first-expiry-first-out (FEFO) stock rotation was demonstrated in **91 pharmacies (75.8%)**.

Complete agreement between selected physical stock and recorded stock quantities was demonstrated in 88 pharmacies (73.3%). Twelve pharmacies demonstrated discrepancies involving at least one selected medicine.

The mean inventory-record accuracy was **91.8 ± 6.4%**.

Table 4. Storage and Inventory-Management Indicators

Indicator	Pharmacies demonstrating practice	Percentage
Appropriate medicine storage	101	84.2
Expiry monitoring documented	96	80.0
FEFO stock rotation	91	75.8
Complete stock-record reconciliation	88	73.3
Appropriate segregation of damaged/expired stock	94	78.3
Mean inventory-record accuracy ± SD	—	91.8 ± 6.4

Interpretation of stock reconciliation: The 88 pharmacies represented outlets in which the selected physical stock quantities matched their corresponding records. The remaining 32 pharmacies did not demonstrate complete matching across the selected medicines. The mean inventory-record accuracy of 91.8 ± 6.4% was calculated at the medicine-record level rather than from the percentage of pharmacies demonstrating complete reconciliation.

Documentation and Professional-Service Practices

Complete and readily retrievable prescription-related documentation was demonstrated in **86 pharmacies (71.7%)**. Complete restricted-medicine documentation was available in **89 pharmacies (74.2%)**, while purchase/sales documentation was readily retrievable in **94 pharmacies (78.3%)**.

Patient counselling was comparatively less consistent. Dose and administration counselling was demonstrated in 87 pharmacies (72.5%), precaution/adverse-effect counselling in 62 (51.7%), adherence counselling in 69 (57.5%), and medicine-related patient information in 76 (63.3%).

Table 5. Documentation and Professional Service Performance

Parameter	Pharmacies demonstrating practice	Percentage
Complete prescription documentation	86	71.7
Complete restricted-medicine documentation	89	74.2
Purchase/sales documentation readily retrievable	94	78.3
Dose and administration counselling	87	72.5
Precaution/adverse-effect counselling	62	51.7
Adherence counselling	69	57.5
Medicine-related patient information provided	76	63.3

Operational-Efficiency Performance

The mean operational-efficiency score was **15.90 ± 2.40 out of 20**, corresponding to **79.5%**.

The mean prescription-processing time was **4.8 ± 1.3 min**. The mean inventory-record accuracy was **91.8 ± 6.4%**, whereas documentation completeness was **74.6 ± 11.2%**.

Standardized workflow was demonstrated in **88 pharmacies (73.3%)**, while **31 pharmacies (25.8%)** reported or demonstrated frequent workflow interruption.

Table 6. Operational-Efficiency Indicators

Operational indicator	Result
Operational-efficiency score	15.9 ± 2.4/20
Operational efficiency	79.5%
Mean prescription-processing time	4.8 ± 1.3 min
Inventory-record accuracy	91.8 ± 6.4%
Documentation completeness	74.6 ± 11.2%
Pharmacies with standardized workflow	88 (73.3%)
Pharmacies reporting frequent workflow interruption	31 (25.8%)

Regulatory-Compliance Categories and Operational Efficiency

Among the 120 pharmacies, **49 (40.8%)** demonstrated high regulatory compliance, **56 (46.7%)** demonstrated moderate compliance and **15 (12.5%)** demonstrated low compliance.

The high-compliance group had the highest mean operational-efficiency score, whereas the low-compliance group had the lowest score.

Table 7. Regulatory-Compliance Category and Operational-Efficiency Performance

Compliance category	Pharmacies, (%)	n	Mean score	operational-efficiency	Mean efficiency (%)
High (≥80%)	49 (40.8)		17.2 ± 1.5		86.0
Moderate (60–79%)	56 (46.7)		15.3 ± 1.8		76.5
Low (<60%)	15 (12.5)		12.9 ± 2.0		64.5
Overall	120 (100.0)		15.9 ± 2.4		79.5

The observed pattern indicates that pharmacies with stronger regulatory-compliance scores also tended to demonstrate better operational organization.

Association Between Regulatory Compliance and Operational Efficiency

Pearson correlation analysis demonstrated a positive association between overall regulatory compliance and operational efficiency ($r = 0.68$, $p < 0.001$).

Positive associations were also observed between regulatory compliance and inventory-record accuracy ($r = 0.55$), documentation completeness ($r = 0.63$), prescription-processing efficiency ($r = 0.49$) and workflow standardization ($r = 0.61$).

These findings indicate that higher regulatory-compliance scores tended to occur alongside more favorable operational indicators. However, because several operational indicators may conceptually overlap with compliance-related practices, the strength of these relationships should be interpreted cautiously.

Table 8. Association Between Regulatory Compliance and Selected Operational Indicators

Variable	Pearson's r with compliance score	Interpretation
Overall operational-efficiency score	0.68	Positive association
Inventory-record accuracy	0.55	Positive association
Documentation completeness	0.63	Positive association
Prescription-processing efficiency	0.49	Positive association
Workflow standardization	0.61	Positive association

DISCUSSION

The present study examined the association between regulatory compliance and operational efficiency among community pharmacies in India. The overall regulatory-compliance score was 78.0%, indicating that the assessed pharmacies generally demonstrated compliance with a substantial proportion of the evaluated requirements. However, meaningful differences were observed across individual domains.

Legal and pharmacist-related compliance demonstrated the highest domain score (88.4%). This suggests that fundamental requirements relating to pharmacist registration, availability and statutory pharmacy conditions were comparatively well established. Prescription and dispensing compliance was also relatively high (80.3%), indicating that core prescription-handling procedures were demonstrated in most assessed pharmacies.

In contrast, documentation and professional-service domains demonstrated comparatively lower scores. Documentation compliance was 72.2%, while professional services recorded 68.0%. These findings are important because regulatory compliance in community pharmacy extends beyond licensing and medicine sale and includes traceability, professional conduct and patient-oriented services.

Prescription verification was demonstrated in 87.5% of pharmacies. Nevertheless, systematic documentation of dose, strength, duration and patient-related information was not consistently demonstrated. This finding indicates a distinction between performing a professional activity and maintaining adequate documentary evidence of that activity.

Restricted medicine practices also showed room for improvement. Schedule H/H1/X handling requirements were demonstrated in 78.3% of pharmacies, while systematic Schedule H1 documentation was demonstrated in 74.2%. Since restricted-medicine documentation provides traceability and supports regulatory accountability, deficiencies in this area may represent an important management concern.

Storage and inventory practices were generally favorable. Appropriate storage was demonstrated in 84.2% of pharmacies, expiry monitoring in 80.0%, and FEFO stock rotation in 75.8%. However, only 73.3% of pharmacies demonstrated complete reconciliation of the selected physical stock records. The mean inventory-record accuracy was nevertheless high at $91.8 \pm 6.4\%$, indicating that most individual stock records were accurate despite some pharmacies having at least one discrepancy.

Documentation completeness remained comparatively weaker than inventory-record accuracy. The mean

documentation-completeness score was $74.6 \pm 11.2\%$. Complete prescription documentation was demonstrated in 71.7% of pharmacies, while complete restricted-medicine documentation was demonstrated in 74.2%. These findings highlight the importance of standardized documentation systems and periodic record audits.

Patient counselling was the weakest component among several professional-service indicators. Dose and administration counselling was demonstrated in 72.5% of pharmacies, whereas precaution/adverse-effect counselling was observed in only 51.7% and adherence counselling in 57.5%. These findings are consistent with previous Indian research identifying knowledge, confidence, time and system-related barriers to community pharmacist counselling [11].

The mean operational-efficiency score was 79.5%. The high-compliance group demonstrated the highest operational-efficiency score (86.0%), while the low-compliance group demonstrated the lowest (64.5%). This pattern suggests that better-organized regulatory practices tend to coexist with better operational organization.

The overall Pearson correlation between regulatory compliance and operational efficiency was $r = 0.68$ ($p < 0.001$). This represents a positive association, indicating that pharmacies with higher compliance scores tended to have higher operational-efficiency scores.

However, this association should be interpreted cautiously. Several elements of the operational-efficiency assessment, particularly documentation, prescription verification, inventory management and restricted-medicine handling, may overlap conceptually with the regulatory-compliance checklist. Such overlap can artificially increase the observed correlation because the two measures may partly capture similar underlying practices.

Therefore, the correlation should not be interpreted as evidence that regulatory compliance directly causes improved operational efficiency. Instead, it indicates that stronger compliance and stronger operational organization were observed together in the assessed pharmacies.

The findings have practical relevance for pharmacy management. Regulatory compliance may be incorporated into routine management through internal audits, standardized operating procedures, prescription-verification protocols, inventory reconciliation, expiry monitoring, staff training and systematic documentation. Digital documentation systems may also support record retrieval and traceability when implemented appropriately.

Theoretical and Practical Implications

The findings support a pharmacy-management perspective in which regulatory requirements are considered part of routine operational governance rather than merely inspection-related obligations.

From a management perspective, standardized compliance procedures may provide a framework for organizing workflow, maintaining records and supporting accountability. From a legal perspective, systematic documentation and appropriate restricted-medicine handling provide traceability and support adherence to applicable regulatory requirements.

For pharmacy managers, the results indicate several priority areas:

- regular internal compliance audits;
- standardized prescription-verification procedures;
- systematic Schedule H/H1/X documentation;
- regular stock reconciliation;
- expiry monitoring and FEFO implementation;
- pharmacist-focused continuing education;
- standardized patient-counselling procedures; and
- appropriate digital record-management systems.

Limitations

The study has several limitations.

First, the cross-sectional design permits assessment of association but does not establish temporal order or causality. Therefore, the observed relationship between regulatory compliance and operational efficiency should not be described as an impact or causal effect.

Second, convenience sampling was used, which limits generalizability beyond the assessed pharmacies.

Third, the study included urban and semi-urban pharmacies, but the supplied study record does not provide sufficient state- or city-level sampling information to establish geographical representativeness.

Fourth, the number of pharmacies approached, refused or excluded before inclusion was not documented in the supplied study record. Consequently, a response rate cannot be reliably calculated.

Fifth, the operational-efficiency tool contains several items that may overlap conceptually with the regulatory-compliance checklist. This construct overlap may have contributed to the observed correlation. A sensitivity analysis using non-overlapping operational indicators would strengthen the evidence.

Sixth, the study did not report adjusted analyses controlling for pharmacy type, location, years of operation, staffing level, prescription volume or digital-system use. These factors may influence both compliance and operational performance.

Seventh, the study did not report formal inter-rater reliability, construct-validity statistics or a formal psychometric validation of the assessment instruments.

Finally, although confidentiality procedures were described, the supplied study record does not contain a formal ethics approval/exemption number.

CONCLUSION

The present study demonstrated a positive association between regulatory compliance and operational efficiency among the assessed community pharmacies in India. The mean regulatory-compliance score was 78.0%, while the mean operational-efficiency score was 79.5%.

Pharmacies with higher compliance scores tended to demonstrate better operational organization, including more favorable workflow standardization, inventory-record accuracy, documentation and prescription-processing indicators. The overall association between regulatory compliance and operational efficiency was statistically significant ($r = 0.68$, $p < 0.001$).

The findings particularly identified documentation, professional services, restricted-medicine record maintenance and patient counselling as areas requiring continued managerial attention.

However, the findings should be interpreted as associations rather than causal effects because of the cross-sectional design. In addition, conceptual overlap between some compliance and operational-efficiency indicators may have contributed to the observed strength of association.

Community pharmacies may benefit from integrating regulatory requirements into routine management systems through standardized operating procedures, pharmacist training, internal compliance audits, prescription-verification protocols, expiry monitoring, stock reconciliation, patient-counselling procedures and appropriate digital documentation.

Future studies should employ probability-based sampling where feasible, clearly distinct measurement instruments, larger geographical coverage and multivariable analyses incorporating pharmacy characteristics and workload-related factors.

DATA AVAILABILITY STATEMENT

The dataset generated and/or analyzed during the study should be made available from the corresponding author on reasonable request, subject to confidentiality requirements and applicable institutional policies. Where ethically permissible, an anonymized dataset containing pharmacy-level compliance and operational-efficiency variables may be deposited in an appropriate research repository to facilitate

reproducibility.

ETHICS STATEMENT

Participation by pharmacy personnel was voluntary. Confidentiality was maintained, individual pharmacy identities were not included in the analytical dataset, and no personal patient-identifying information was recorded.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

REFERENCES

1. Basak, S. C.; Sathyanarayana, D. Community Pharmacy Practice in India: Past, Present and Future. *South. Med. Rev.* **2009**, *2* (1), 11–14.
2. Government of India. *The Pharmacy Act, 1948*; Ministry of Health and Family Welfare, New Delhi, India, 1948.
3. Government of India. *The Drugs and Cosmetics Act, 1940*; Ministry of Health and Family Welfare, New Delhi, India, 1940.
4. Pharmacy Council of India. *Pharmacy Practice Regulations, 2015*; New Delhi, India, 2015.
5. World Health Organization; International Pharmaceutical Federation. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services*; WHO Technical Report Series No. 961, Annex 8; World Health Organization: Geneva, 2011.
6. Government of India, Ministry of Health and Family Welfare. Rules for Selling of Drugs under Schedule H1; Press Information Bureau, New Delhi, 2013.
7. Government of India, Ministry of Health and Family Welfare. Pregabalin Classified under Schedule H1 of the Drugs Rules, 1945; Press Information Bureau, New Delhi, 2026.
8. Kumar, K. S.; Saranya, S.; Rani, N. V. Community Pharmacists' Knowledge, Attitude, and Nonprescription Dispensing Practices of Antibiotics: An Explorative Study in a Selected City of South India. *J. Res. Pharm. Pract.* **2022**, *11* (2), 51–58. DOI: 10.4103/jrpp.jrpp_48_21.
9. Dharanindra, M.; et al. Antibiotic-Dispensing Patterns and Awareness of Anti-microbial Resistance Among the Community Pharmacists in South-Central India. *Cureus* **2023**, *15*. DOI: 10.7759/cureus.47043.
10. Chatterjee, P.; et al. What Drives Inappropriate Antibiotic Dispensing? A Mixed-Methods Study of Pharmacy Employee Perspectives in Haryana, India. *BMJ Open* **2017**, *7*, e013190. DOI: 10.1136/bmjopen-2016-013190.
11. Bawaskar, H. S.; et al. Attitudes and Behaviors of Practicing Community Pharmacists towards Patient Counselling. *Indian J. Pharm. Sci.* **2009**, *71*. DOI: 10.4103/0250-474X.56029.
12. Kotwani, A.; Wattal, C.; Joshi, P. C.; Holloway, K. Irrational Use of Antibiotics and Role of the Pharmacist: An Insight from a Qualitative Study in New Delhi, India. *J. Clin. Pharm. Ther.* **2012**, *37*, 308–312. DOI: 10.1111/j.1365-2710.2011.01293.x.