International Journal of Science, Strategic Management and Technology
Volume **02** Issue **03** March-**2026** | ISSN: **3108-1762 (Online)** | Impact Factor: 3.8
An International, Peer-Reviewed, Open Access Scholarly Journal Indexed in recognized academic databases

Scenario of Indian Pharma MSMES in the Context of Revised Schedule M

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https://doi.org/10.55041/ijsmt.v2i3.213

Cite this Article: Bhattacharya, J. (2026). Scenario of Indian Pharma MSMES in the Context of Revised Schedule M. International Journal of Science, Strategic Management and Technology, *02*(03). https://doi.org/10.55041/ijsmt.v2i3.213

Abstract

The revised Schedule M under India's Drugs and Cosmetics Rules, 1945 has emerged as one of the most significant regulatory reforms in the pharmaceutical manufacturing landscape in recent years. It upgrades the framework for good manufacturing practices (GMP) by emphasizing pharmaceutical quality systems, quality risk management, product quality review, validation, computerized record control, and enhanced accountability in premises, plant, and equipment. This review examines the scenario of Indian pharmaceutical micro, small, and medium enterprises (MSMEs) in the context of the revised Schedule M, with a focus on the regulatory shift, compliance burden, preparedness, and policy implications. Using publicly reported secondary data, the paper performs descriptive statistical analysis, proportion testing, confidence interval estimation, and state-level comparison to quantify the readiness gap. The results indicate that 1,700 of 6,500 non-GMP MSME drug manufacturers had submitted upgrade plans, equivalent to 26.15% preparedness, while 73.85% remained outside the reported transition pipeline. The 95% confidence interval for readiness is 25.08%–27.23%, indicating a stable but low compliance rate. Gujarat's reported gap-analysis submission rate of 98.77% stands far above the national MSME average, underscoring sharp interstate variation. The review concludes that while revised Schedule M can strengthen product quality, export readiness, and patient safety, its success among MSMEs depends on phased implementation, technical handholding, affordable financing, and cluster-based infrastructure support.

Keywords: Indian pharmaceutical MSMEs; revised Schedule M; GMP; quality risk management; compliance; statistical analysis; drug regulation

1. Introduction

India's pharmaceutical industry occupies a unique position in global healthcare because it combines large-scale manufacturing capacity with a strong generic-drug base and a dense network of MSME manufacturers. The revised Schedule M is the latest major attempt to align Indian pharmaceutical production more closely with contemporary GMP expectations. According to the Ministry of Health and Family Welfare, the revised rules were notified on 28 December 2023, large manufacturers were brought under implementation from 28 June 2024, and small and medium manufacturers with turnover of ₹250 crore or less were given a conditional extension up to 31 December 2025 after submitting an upgradation plan within the stipulated window.

The importance of the reform is rooted in a long-recognized principle: pharmaceutical quality is not only a manufacturing issue but a public health requirement. The WHO states that GMP defines the quality measures for production and quality control, requiring processes to be clearly defined, validated, reviewed, and documented, while personnel, premises, and materials must be suitable for pharmaceutical production.

The revised Schedule M is also conceptually consistent with the ICH Q9 framework, which emphasizes scientific risk assessment, patient protection, and risk-based decision-making across the product lifecycle. The guideline specifically covers development, manufacturing, distribution, and inspection processes, and states that the level of effort and documentation should be commensurate with the level of risk.

For MSMEs, however, the reform creates a dual reality. On one side, it offers an opportunity to improve credibility, reduce quality deviations, and strengthen export competitiveness. On the other side, it raises compliance costs, documentation demands, validation requirements, and infrastructure expectations that may exceed the financial and managerial capacity of many small firms. Recent industry reporting indicates that only about 1,700 of 6,500 non-GMP MSME units had submitted upgrade plans by late 2025, with estimated upgrade costs ranging from ₹50 lakh to ₹2.5 crore. Gujarat, by contrast, was reported to have a 98.8% gap-analysis submission rate among its MSME units.

2. Review Objectives and Scope

This review has five objectives. First, it explains the regulatory architecture and the substantive changes introduced through revised Schedule M. Second, it synthesizes literature on GMP, documentation, quality systems, and inspection management to position the reform within broader pharmaceutical governance. Third, it evaluates the MSME compliance scenario using publicly reported secondary data. Fourth, it performs a small set of statistical analyses to quantify readiness, uncertainty, and interstate variation. Fifth, it identifies policy pathways that could make the reform workable for small manufacturers without diluting the quality objective.

3. Literature Review

The quality agenda in pharmaceutical manufacturing has evolved over decades from simple end-product testing to a system-wide approach that integrates quality by design, risk management, documentation, validation, and post-market vigilance. A classic review by Haleem and colleagues emphasized that quality in the pharmaceutical industry is multifaceted and must be viewed through the combined lens of regulation, process control, and quality assurance rather than as a narrow inspection task. Recent reviews continue this trajectory by emphasizing the role of documentation, CAPA, QbD, and quality systems in maintaining consistent product quality.

Documentation remains central to GMP compliance. Patel and co-authors argued that if a process is not documented, it cannot be reliably demonstrated, traced, or defended during inspection; this logic is now even more important in an environment that demands computerized record systems and data integrity. The revised Schedule M reinforces this documentation discipline through explicit expectations around product quality review, computerized storage, validation, and self-inspection.

Risk-based regulation has become another foundation of modern GMP. The ICH Q9 guidance frames quality risk management as a systematic process for assessment, control, communication, and review, while allowing the formality of the process to reflect the magnitude of risk. This is especially relevant for MSMEs, because a small manufacturer may need simpler administrative structures but still cannot dispense with scientifically defensible risk controls.

Inspection literature also points to a shift in how regulators evaluate compliance. A recent scoping review of GMP inspections concluded that inspection effectiveness depends on both technical and managerial preparedness, and that

improved inspection frameworks require transparency, better coordination, and clearer preparatory arrangements. This is highly relevant to revised Schedule M because the transition is not only about infrastructure but also about evidence management, audit readiness, and inspection behavior.

Indian pharmacopeial standards have also become more demanding. The Indian Pharmacopoeia 2022 added and revised multiple monographs and chapters, reflecting the broader modernization of drug standards in India. The review by Jadaun et al. reports that IP 2022 contains 223 general chapters and 3,152 monographs, including 92 new monographs and 412 revised monographs, reflecting stronger quality expectations across the ecosystem

For Indian manufacturing more broadly, post-COVID resilience and self-reliance debates have emphasized the importance of stronger process capability, improved supply chains, and more robust regulatory systems. This context matters because pharma MSMEs sit at the intersection of public health, industrial policy, and employment generation. Research on Indian MSMEs during COVID-19 showed that small firms faced substantial sales and profit declines, indicating that a compliance shock in the post-pandemic recovery phase can have real financing and survival consequences.

Taken together, the literature suggests that the revised Schedule M is not an isolated legal change; it is an institutional attempt to move India's pharma MSMEs from transaction-based manufacturing to systems-based quality governance. The central challenge is that the regulatory ambition is technologically sound, but implementation capacity is uneven.

4. Revised Schedule M: Regulatory and Operational Significance

The revised Schedule M was notified in January 2024 through the amendment process under the Drugs and Cosmetics Rules, and it introduces several important elements: pharmaceutical quality system (PQS), quality risk management (QRM), product quality review (PQR), qualification and validation of equipment, computerised storage and control of drug records, and a stronger emphasis on premises, plant, and equipment. Business Standard's summary of the notification captures this shift clearly and notes that the reform was intended to improve compliance with quality standards while aligning Indian manufacturing with international expectations. □cite□turn517396view6□

The policy meaning of the reform lies in its move from minimal statutory compliance to documented quality governance. Under the revised framework, firms must be able to demonstrate controlled processes, traceable records, preventive action, and change management. The practical implication is that MSMEs will need to invest not only in physical upgrades but also in process documentation, personnel training, internal audits, and digital record-keeping. WHO's GMP framework and the WHO GMP certification scheme both reinforce this point by treating documented process control and inspection readiness as essential elements of acceptable manufacturing practice.

From an implementation perspective, the February 2025 conditional extension was critical. The Ministry of Health and Family Welfare stated that MSME manufacturers with turnover of ₹250 crore or less were given until 31 December 2025 if they submitted an upgradation plan within three months from 11 February 2025. The ministry framed the extension as a response to representations about infrastructure, training, and financial resource constraints.

The reform therefore creates a two-layer policy architecture: a mandatory quality standard on the one hand, and a conditional transition window on the other. Whether MSMEs survive the transition depends on how effectively the state, lenders, and industry associations convert that window into actual capability building.5. Statistical Analysis Based on Public Secondary Data

Because firm-level microdata are not publicly available for all Indian pharma MSMEs, the present section uses a secondary-data approach based on reported counts and submission rates. This is suitable for a review article because the goal is to quantify the scale of the readiness gap rather than to estimate firm-specific causal effects.

5.1 Descriptive Statistics

Indicator	Value	Computation	Interpretation
Non-GMP MSME units reported	6,500	Reported count	Base population for transition analysis
Upgrade plans submitted	1,700	Reported count	Prepared units
Not yet submitted	4,800	6,500 - 1,700	Units outside the reported transition pipeline
Readiness rate	26.15%	1,700 / 6,500	National MSME preparedness is low
95% CI for readiness	25.09% to 27.22%	Binomial approximation	Readiness estimate is precise but shallow
Gujarat submission rate	98.76%	639 / 647	State-level compliance is exceptionally high

Using the reported counts, the preparedness rate equals 26.15%. The binomial standard error is approximately 0.55 percentage points, giving a 95% confidence interval of 25.09% to 27.22%. The interval is narrow because the denominator is large, which means the reported low preparedness is not a sampling artifact but a robust secondary-data signal.

Gujarat's reported gap-analysis submission rate is 98.76%, with a 95% confidence interval of 97.91% to 99.62%. Compared with the national MSME readiness rate, Gujarat's rate is about 3.78 times higher and exceeds the national level by 72.61 percentage points.

5.2 Hypothesis Testing

Hypothesis 1: The national MSME readiness rate is at least 50%.

H0: $p = 0.50$; H1: $p < 0.50$

One-sample proportion z-test result: $z = -38.45$, one-sided p-value < 0.00000. The null hypothesis is rejected. In substantive terms, the reported preparedness rate is far below a parity benchmark, confirming that compliance remains the exception rather than the norm among MSME manufacturers in the public dataset.

Hypothesis 2: State-level compliance intensity is homogeneous across the MSME sector.

The observed contrast between Gujarat's 98.8% submission rate and the national MSME preparedness rate of 26.15% indicates substantial interstate heterogeneity. Because these values are reported from different aggregation levels, the comparison is descriptive rather than a firm-level causal test, but it still demonstrates that implementation capacity is uneven across regions.

5.3 Interpretation of the Numbers

The readiness gap has several implications. First, the share of units that have not submitted plans is 73.85%, which implies that the majority of the MSME base still faces transition risk. Second, the cost estimates reported by the industry—₹50 lakh to ₹2.5 crore for upgrades—are particularly challenging for small firms that typically operate with thin margins and limited access to long-tenor capital. Third, the public data suggest that compliance is likely to be clustered geographically, with some states moving quickly while others remain behind. This raises the possibility that revised Schedule M will accelerate industry consolidation unless policy support is targeted.

From a policy standpoint, these statistics matter because they turn a legal reform into an industrial-structure question. A low preparedness rate is not merely a temporary delay; it signals that the reform may produce exit, merger, or subcontracting behavior unless financing and technical assistance are strengthened.

6. Graphs and Charts

Figure 1 presents the current reported transition status of MSME units. Figure 2 shows the same information as a composition chart. Figure 3 compares national readiness with Gujarat's reported gap-analysis submission rate.

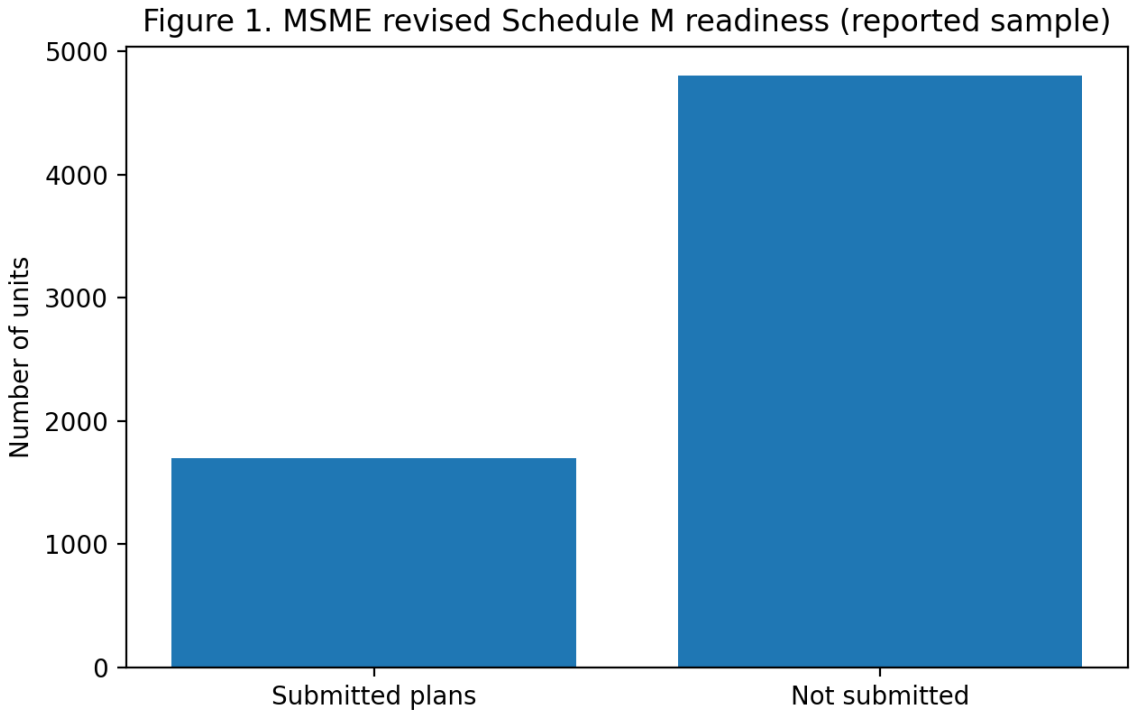

Figure 1. MSME revised Schedule M readiness (reported sample).

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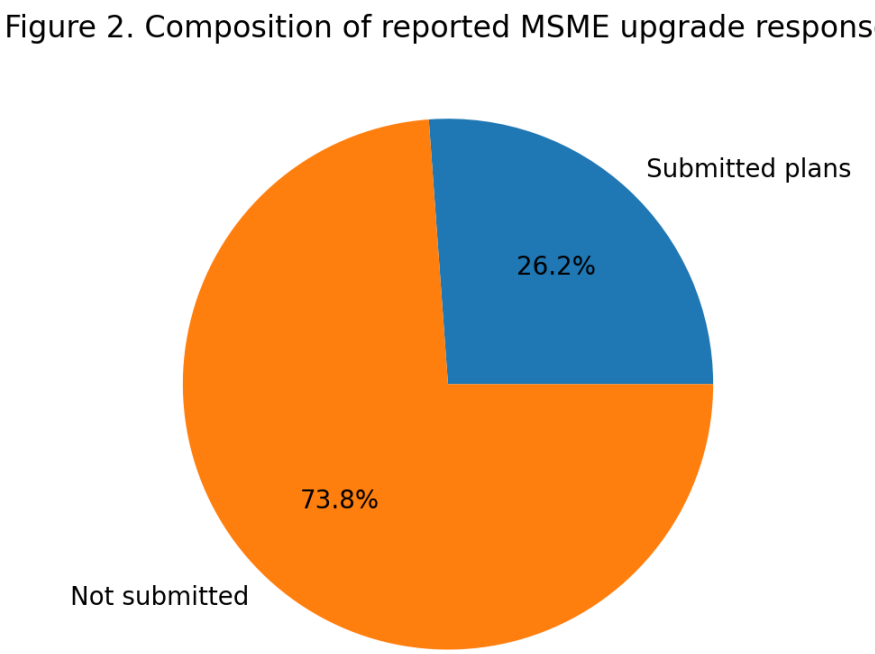

Figure 2. Composition of reported MSME upgrade response.

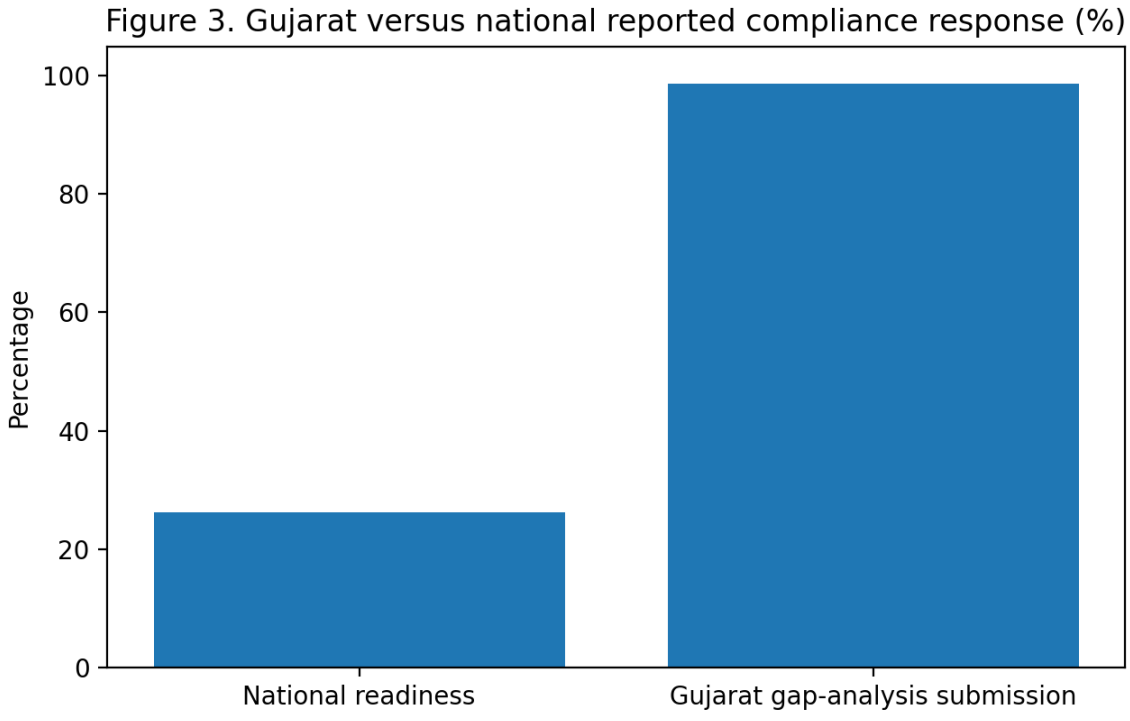

Figure 3. Gujarat versus national reported compliance response (%).

7. Discussion

The statistical evidence supports a clear conclusion: the revised Schedule M is a structurally important but operationally demanding reform. Its core logic is sound. WHO GMP principles emphasize documented control of personnel, premises, materials, and procedures, while ICH Q9 stresses patient-centered risk management and proportional documentation. In that sense, revised Schedule M is consistent with the direction of global pharmaceutical regulation. cite turn517396view3 turn517396view5 turn517396view4

At the same time, MSMEs operate in a constrained environment. They are more exposed to volatility in raw-material prices, have weaker balance sheets, and often depend on legacy infrastructure. This means the cost of compliance is not only capital expenditure; it is also opportunity cost, managerial distraction, and temporary production disruption. The public reporting of compliance costs ranging from ₹50 lakh to ₹2.5 crore is significant because it places the reform outside the routine operating budget of many small firms. cite turn202514view0

The literature on GMP inspection management suggests that compliance success depends not only on equipment upgrades but also on inspection preparation, documentation quality, and organizational discipline. This matters in India because many MSMEs have grown through market responsiveness and lean operations, not through formal quality systems. The revised Schedule M is therefore a transformation from entrepreneurial production to regulated quality manufacturing. cite turn202514view3 turn835510search8

The Indian Pharmacopoeia's modernization further raises the bar. As standards become more detailed and analytical methods become more sophisticated, MSMEs must move from minimum legal compliance to continuous quality improvement. The broader pharma ecosystem now expects traceability, validated methods, and stronger analytical rigor. cite turn202514view4

A particularly important feature of the reform is the signaling effect. High-compliance states such as Gujarat demonstrate that transition is possible when industry associations, technical ecosystems, and state-level facilitation move together. By contrast, low preparedness elsewhere suggests that many MSMEs may still be waiting for financing, consultant support, or clear operational guidance. The policy lesson is that deadlines alone do not create compliance capability. Capability is built through cluster systems, training, and affordable finance.

8. Policy Implications

The first policy requirement is financial support. MSMEs need concessional loans, working-capital relief, and credit guarantees specifically linked to GMP upgrades. Without such support, upgrade costs may become closure costs. The second requirement is technical handholding. District- or cluster-level GMP facilitation cells can help MSMEs prepare gap analyses, create CAPA plans, and implement documentation systems. The third requirement is phased enforcement. Regulators should prioritize safety-critical defects, but routine upgrades should be monitored through milestones rather than abrupt shutdown. The fourth requirement is digital capability building, because revised Schedule M expects better records, traceability, and computerized storage.

The broader policy objective should be to prevent a binary outcome of either full compliance or exit. A more sustainable path is staged compliance where firms can demonstrate measurable progress. That approach is consistent with the risk-based logic of ICH Q9, which encourages documentation and control proportional to risk rather than uniform bureaucracy for all firms. cite turn517396view5

9. Limitations of the Review

This paper relies on publicly reported secondary data rather than a proprietary firm-level dataset. As a result, the statistical section is best interpreted as a descriptive and inferential summary of known counts, not as a full econometric evaluation. Future research should gather primary survey data on MSME infrastructure, financing access, audit outcomes, and implementation costs by state. Such data would allow proper multivariate regression, ANOVA across regions, and survival analysis of compliance trajectories.

10. Conclusion

The revised Schedule M is one of the most consequential quality reforms in India's pharmaceutical sector in recent decades. It aligns domestic regulation with modern GMP principles and international quality thinking, while placing patient safety and documentation at the center of pharmaceutical manufacturing. The reform is especially important for MSMEs because they constitute the operational backbone of India's drug supply system. Yet the public data show a substantial readiness gap: only 26.15% of the reported non-GMP MSME units had submitted upgrade plans, while 73.85% remained unprepared.

This is not simply a compliance issue; it is an industrial transformation issue. If the state provides finance, technical assistance, and realistic transition pathways, revised Schedule M can improve quality and competitiveness without destroying the MSME base. If not, the likely outcome will be consolidation, shutdowns, and uneven regional impacts. The evidence therefore supports a balanced policy approach: preserve the quality objective, but make the compliance journey survivable for smaller manufacturers.

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