Just 1 in 4 MSME pharma units likely ready for GMP transition

Firms not complying with norms risk shutdowns once inspections begin next year

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Only about 1,700, or 26 per cent of India's estimated 6,500 MSME pharmaceutical manufacturers that were required to come up to speed with revised good manufa turing practices (GMP) norms by December 31, are likely to make the cut.

India has around 10,500 pharmaceutical manufacturing units, nearly 8,500 of which fall under the micro, small, and medium enterprise (MSME) category. Around 2,000 MSME units already hold WHO-GMP certification.

This implies that in all, about 3,700 or 43 per cent of MSME drugmakers are likely to comply with the revised Schedule M norms. The rest of the units, thus, risk shutdowns once inspections of their facilities begin next year, industry experts said.

Under the revised Schedule M norms, first notified in 2022, pharma units are required to adopt tighter quality controls, including pharmaceutical quality systems (PQS), quality risk management (QRM), product quality review (PQR), equipment validation and a robust product recall mechanism.

States such as Gujarat and Maharashtra have taken the lead in pharma units submitting gap analysis plans for upgradation, while Himachal Pradesh and Uttar Pradesh have lagged, according to industry sources.

Gujarat, for example, has demonstrated exceptional compliance, with 639 of 647 units successfully submitting their gap analysis — a rate of 98.8 per cent," an industry executive told *Business Standard* on condition of anonymity.

He added that states with high pharma manufacturing activity such as Maharashtra, Andhra Pradesh and Telangana have also seen strong participation from units seeking to upgrade facilities in line with the revised Schedule M of the Drugs and Cosmetics Act.

Compliance check

December 31, 2025: Deadline for implementing revised Schedule M norms

1,700 of 6,500 non-GMP MSME units have submitted upgrade plans

98.8%: MSME units in Gujarat that filed gap analysis; highest in the country

7%: MSME share of the Indian pharma market

₹50 lakh-₹2.5 crore: Estimated cost of compliance upgrades

"Himachal Pradesh, on the other hand, which houses several pharma manufacturing units in clusters like Baddi, saw only about 116 of over 650 units initiating the upgradation process," he said.

Micro and small pharma firms with annual turnover of ₹250 crore or less were granted a one-year extension to comply with the revised norms until December 31, 2025. However, this extension was conditional on conducting a gap analysis and filing an application with the drug regulator outlining a compliance strategy by May 2025. "Of the remaining 6,500 firms, only about 1,700 MSME pharmaceutical units — or 26.15 per cent — have successfully submitted their gap analysis to secure extended timelines," said Rishi Agrawal, co-founder and chief executive officer at TeamLease RegTech.

The MSME units not submitting their plans by the deadline risk shutdown following inspections beginning January. "We will start joint inspections with the Central Drugs Standard Control Organisation in January to check compliance. Under any circumstances, we are not in the mood to give permission to any unit if they are not compliant," said an official with the Delhi drugs control department.

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However, potential closures of non-compliant units are unlikely to disrupt drug supplies in the domestic market, though they may have downstream effects on employment.

"Companies with turnover below ₹250 crore collectively contribute only about 7 per cent of the Indian Pharma Market (IPM). Of these, a few are old, established players focused on niche segments, which is why their turnover is low," said Sheetal Sapale, vice-president (commercial) at market analysis firm Pharmarack.

She added that government action is unlikely to impact drug availability or established small companies, as these are already compliant with GMP norms.

Agrawal said any temporary supply disruption could be absorbed by India's large manufacturing capacity.

"There can be an emergence of GMP-certified contract manufacturing facilities over time, allowing smaller companies that own formulations to outsource production and still remain profitable," he said.

He added that the growth of such players could also offset future job losses, as larger drugmakers and contract manufacturers expand operations, including into rural markets.

SOME DRUGMAKERS HAD SOUGHT FURTHER EXTENSIONS TO ALLOW MORE TIME FOR GENUINE APPLICANTS, BUT INDUSTRY WATCHERS BELIEVE THIS IS UNLIKELY

"We estimate four to six months as the average time needed for implementation, with upgradation costs ranging from ₹50 lakh to ₹2.5 crore, depending on the size, scale and product mix of the unit," Agrawal said.

MSME industry bodies, however, argue that many smaller players have struggled due to capital constraints.

"All forms of upgradation require capital infusion of at least ₹2 crore, including additional land, retrofitting facilities and staff training," said R K Jain, chairman of the small-scale drug producers' body Confederation of Indian Pharmaceutical Industry (CIPI).

Another MSME drug manufacturer said many units operate from single facilities in small premises such as apartments, making it difficult for them to meet the deadline.

Analysts, however, say small-scale firms were given adequate time.

"Only around 180 units applied under the government's revised pharmaceutical technical upgradation assistance scheme (RPTUAS), which offered financial incentives for MSME investments in upgradation," a drug inspector quoted earlier said.

Agrawal said RPTUAS was the government's olive branch to support MSMEs in transition planning and management, given capital constraints.

Some drugmakers had sought further extensions to allow more time for genuine applicants, but industry watchers believe this is unlikely, especially after incidents such as Chhindwara, where at least 22 children died after consuming contaminated cough syrup.

Mid-term exits by independent directors highest since 2017

Those valued at less than ₹100 crore accounted for 142 exits. There were 191 among companies valued between ₹100 crore and ₹1,000 crore. Less than 12 per cent of the exits were from companies with ₹10,000 crore in market capitalisation or above.

Anecdotally, shareholder feedback suggests that the average large company often has reasonably high governance standards while that is not always true for smaller companies, suggested Amit Tandon, founder and managing director of proxy advisory firm Institutional Investor Advisory Services (IiAS) India.

That said, people are becoming more aware of their responsibilities, according to Tandon. "The conversation has shifted from 'it is a privilege' to be on the board of a company to 'it is a responsibility'," he said.

The exits come after a period of churn following regulatory changes capping the stay of an independent director to two consecutive five-year terms. This came following the Companies Act, 2013. There has been increased institutional scrutiny of the number of companies that directors are serving, according to an earlier report by IIAS.

"Global investors, and some domestic investors, are raising concerns on the overboarding of independent directors. Indian regulations allow individuals to hold up to 20 board positions, of which a maximum of 10 can be in public limited companies. Of these 10, Indian regulations allow individuals to hold up to seven board memberships as independent directors in listed companies. For executive directors of listed companies, board memberships have been capped at three in the position of independent directors. The benchmarks globally are much lower," it said.

The sector with the largest number of mid-term cessations is textiles, followed by software and fast-moving