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DMMA warns regulatory burden threatening Gujarat's pharma MSMEs

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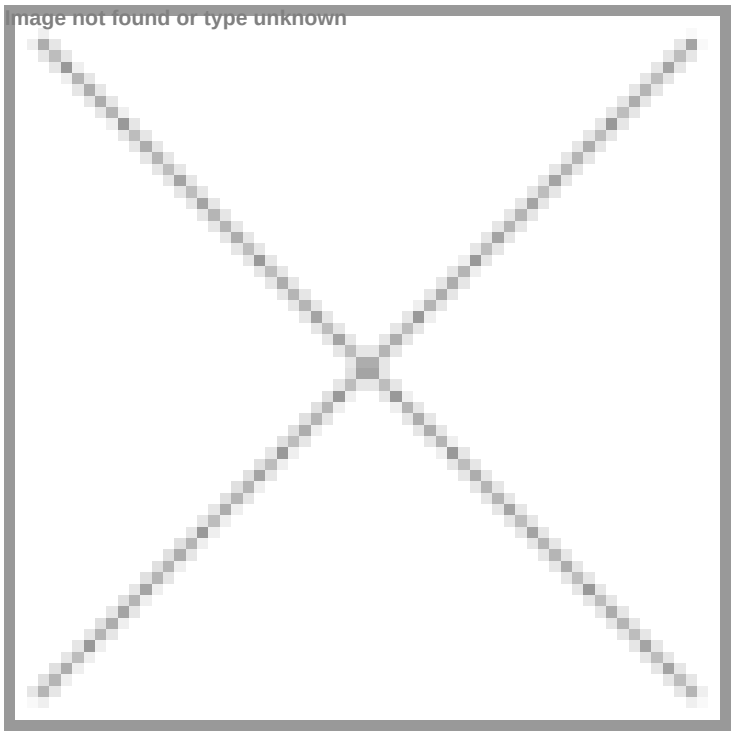
Gujarat is home to approx. 3000 pharmaceutical manufacturing units, over 90% of which are MSMEs



The Drug Marketing and Manufacturing Association (DMMA) has warned that the growing regulatory burden could force widespread closure of small and medium-sized pharmaceutical units in Gujarat and sought urgent government intervention to safeguard the industry. The association has warned that the shutdown of units would have a huge impact on pharma exports and trigger job losses.

Over 30 pharma associations (DMMA, Federation of Pharma Entrepreneurs, Laghu Udyog Bharti, state associations from Himachal (HDMA), Haryana, Karnataka, etc.) have jointly appealed to Union Health Minister JP Nadda and Central Drugs Standard Control Organisation (CDSCO), and submitted a detailed representation outlining the challenges specially withdrawal of the recent directive enforcing bio-equivalence studies under GSR 327 (E).

Each BA/BE study costs Rs 20–40 lakh per product, and MSMEs may have dozens of formulations. This makes compliance financially unviable, saying the lack of officially notified reference products, the high cost of studies, and ethical concerns make compliance impractical and impossible for small units to absorb. Without urgent relief, thousands of units will collapse, leading to medicine shortages nationwide.

The association called for an end to the constant issuance of regulatory circulars that make operations unpredictable and capital-intensive. The association raised alarm over the Revised Schedule M (Good Manufacturing Practices) requirements, slated to come into effect from January 1, 2026. It warned that the expanded scope and costly upgrades, notified without

accommodating the objections of the MSME sector, could force 4,000–5,000 units to close. It demanded that the deadline for companies have a turnover of less than Rs 50 crores should be extended till April 2027.

DMMA objected to risk-based inspections that selectively target MSME units while sparing large corporates, and to the practice of shutting down plants merely based on a manufacturer's own corrective action report if no critical lapses are found.

DMMA President Amit Thakkar said, "Micro, small, and medium enterprises (MSMEs) are the backbone of India's pharmaceutical industry, but they are being burdened by an endless stream of regulatory circulars that run counter to the government's own Ease of Doing Business agenda. While MSME manufacturers will be hit the hardest, these measures will also create shortages of affordable medicines and erode our export competitiveness, allowing other countries to overtake India in global markets."